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(71) Applicant (*for all designated States except US*): **USGI MEDICAL INC.** [US/US]; 1140 Calle Cordillera, San Clemente, California 92673 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **SAADAT, Vahid** [US/US]; 12679 Kane Drive, Saratoga, California 95070 (US). **EWERS, Richard, C.** [US/US]; 1437 West Malvern, Fullerton, California 92833 (US). **PEH, Ruey-feng** [SG/SG]; BLOCK 656, CHOA CHU KANG CRESCENT, Apartment 10-17, Singappore 680656 (SG). **MAAHS, Tracy, D.** [US/US]; 11 Paseo Simpatico, Rancho Santa Margarita, California 92688 (US).

(74) Agent: **BAGADE, Sanjay, S.**; Levine Bagade LLP, Suite 100, 2483 Bayshore Road, Palo Alto, CA 94303 (US).

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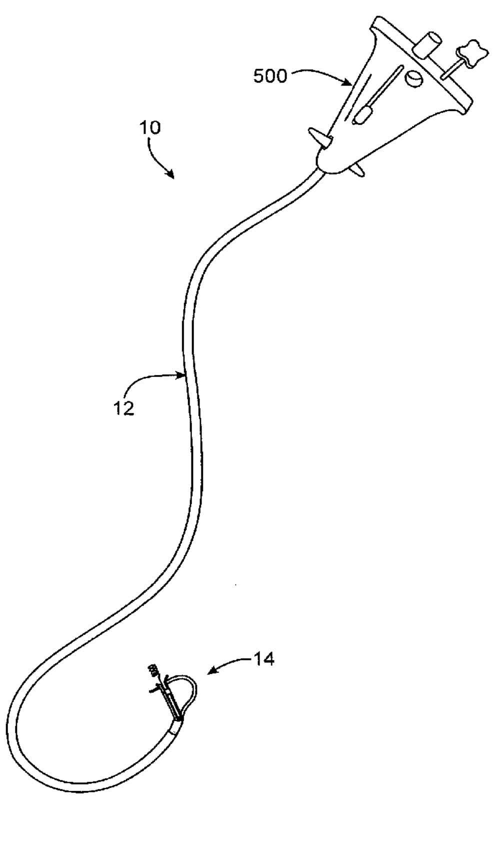

(57) Abstract: Apparatus and methods for conveying or transmitting force or energy to a medical end effector coupled to a flexible or rigid shaft are described herein. One variation of such apparatus may be used to manipulate tissue and create a tissue fold and may generally comprise an elongate tubular member having an end effector disposed thereon. The end effector may comprise a tissue engagement member adapted to engage tissue, a first stabilizing member and a second stabilizing member positioned at the tubular member distal end, and a launch tube adapted to pivot about the first stabilizing member. Elements of the end effector may be actuable via various force transmission elements and/or mechanisms. Such force transmission elements preferably are integrated into and/or are actuable via a handle. The force transmission mechanisms may be utilized to actuate and/or transmit force to alternative medical end effectors coupled to flexible or rigid shafts.

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METHODS AND APPARATUS FOR TRANSMITTING FORCE TO AN END EFFECTOR OVER AN ELONGATE MEMBER

BACKGROUND OF THE INVENTION

[0001] Field of the Invention. The present invention relates to methods and apparatus for conveying or transmitting force to a medical end effector over a flexible or rigid member. The methods and apparatus may, for example, be used to form and secure gastrointestinal ("GI") tissue folds, e.g., to reduce the effective cross-sectional area of a gastrointestinal lumen or otherwise treat a region of gastrointestinal tissue.

[0002] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0003] A number of surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0004] Furthermore, the sutures or staples that are often used in these surgical procedures typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured. The gastrointestinal lumen includes four tissue layers, wherein the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer and the serosa layer.

[0005] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall

during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intra-operatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs.

[0006] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition typically known as a plication. Another method involves manually creating sutures for securing the plication.

[0007] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a maximum level of confidence.

[0008] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping through tissue.

[0009] Many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally. This may be due to difficulties in applying, deploying and/or deforming such devices with low-profile end effectors disposed at significant distances from a medical practitioner, i.e., due to an inability to convey adequate force to the devices and/or end effectors along desired vectors across the significant distances. These difficulties may be exacerbated when the end effectors are coupled to the distal ends of flexible shafts. It is expected that enhanced capabilities for transmitting or

conveying force to a medical device end effector coupled to a flexible or rigid shaft would facilitate myriad minimally invasive procedures, such as endoluminal treatment for morbid obesity.

BRIEF SUMMARY OF THE INVENTION

[0010] In creating tissue plications, a tissue plication tool having a distal tip may be advanced (transorally, transgastrically, etc.) into the stomach. The tissue may be engaged or grasped, and the engaged tissue may be moved to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size. In order to first create the plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic or laparoscopic endoluminal apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0011] One variation of an apparatus that may be used to manipulate tissue and create a tissue fold may generally comprise an elongate tubular member having a proximal end, a distal end, and a length therebetween; and an end effector. The end effector may comprise a tissue engagement member in one variation, which is slidably disposed through the tubular member, having a distal end adapted to engage tissue, an upper or first stabilizing member and a lower or second stabilizing member positioned at the tubular member distal end and adapted to stabilize tissue therebetween, and a launch tube adapted to pivot about the first stabilizing member. The first and second stabilizing members preferably are adapted to be angled relative to a longitudinal axis of the elongate tubular member.

[0012] The end effector may be manipulated and articulated through various mechanisms. One such assembly that integrates each of the functions into a singular unit may comprise a handle assembly, which is connected via the tubular member to elements of the end effector. Such a handle assembly optionally may be configured to separate from the tubular member, thus allowing for reusability of the handle. An articulation control may also be positioned on the handle to provide for selective articulation of the extension members and/or other elements of the end effector.

[0013] One particular variation of the handle assembly may have a handle enclosure formed in a tapered configuration, which is generally symmetrically-shaped about a

longitudinal axis extending from the distal end to the proximal end of the handle assembly. The symmetric feature may allow for the handle to be easily manipulated by the user regardless of the orientation of the handle enclosure during a tissue manipulation procedure.

[0014] To articulate the multiple features desirably integrated into a singular handle assembly, e.g., advancement and/or deployment of the launch tube, anchor assembly, needle assembly, articulation of the extension members and end effector, etc., a specially configured locking mechanism may be located within the handle enclosure. Such a locking mechanism may generally be comprised of an outer sleeve disposed about inner sleeve where the outer sleeve has a diameter, which allows for its unhindered rotational and longitudinal movement relative to the inner sleeve. A needle deployment locking control may extend radially from the outer sleeve and protrude externally from the enclosure for manipulation by the user. The outer sleeve may also define a needle assembly travel path along its length. The travel path may define the path through which the needle assembly may traverse in order to be deployed.

[0015] The needle assembly may define one or more guides protruding from the surface of the assembly, which may be configured to traverse within the travel path. The inner sleeve may also define guides protruding from the surface of the inner sleeve for traversal within grooves defined in the handle enclosure. Moreover, the outer sleeve is preferably disposed rotatably about the inner sleeve such that the outer sleeve and inner sleeve are configured to selectively interlock with one another in a corresponding manner when the locking control is manipulated into specified positions.

[0016] Elements of the end effector may be actuable via various force transmission elements described hereinafter. Such force transmission elements optionally may be integrated into and/or actuable via the handle. It should be understood that the force transmission elements optionally may be utilized to actuate and/or convey force to alternative medical end effectors coupled to flexible or rigid shafts.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Fig. 1A shows a side view of one variation of a tissue plication apparatus which may be used to create tissue plications and to deliver cinching or locking anchors into the tissue.

[0018] Figs. 1B and 1C show detail side and perspective views, respectively, of the tissue approximation assembly of the device of Fig. 1A.

[0019] Figs. 2A to 2D show side views, partially in section, of the tissue plication apparatus of Figs. 1 creating a tissue plication.

[0020] Fig. 3A shows a cross-sectional side view of an anchor delivery assembly delivering a basket-type anchor into or through a tissue fold.

[0021] Fig. 3B shows a cross-sectional side view of multiple tissue folds which may be approximated towards one another and basket anchors as being deliverable through one or both tissue folds.

[0022] Figs. 4A and 4B show side views of one variation of the tissue manipulation assembly having cam-actuated extension members.

[0023] Figs. 4C and 4D show detail views of the cam-actuation for the assembly of Figs. 4A and 4B.

[0024] Figs. 5A and 5B show side views of another variation of extension members which are biased towards one another.

[0025] Figs. 6A and 6B show side views of another variation of extension members which are actuated via a linkage assembly.

[0026] Figs. 7A to 7C show side views of another variation of extension members which are actuatable via one or more hinged arms interconnecting the extension members.

[0027] Figs. 8A and 8B show side views of another variation where one or more extension members are biased away from one another.

[0028] Figs. 9A and 9B show side views of another variation where one or more extension members are configured to be passively biased.

[0029] Figs. 10A and 10B show side views of another variation of extension members which are actuatable via a translatable sleeve.

[0030] Fig. 11 shows a side view of a tissue manipulation assembly with a lower extension member having a longer length than the upper extension member.

[0031] Fig. 12 shows a side view of another variation where one or both extension members may have tips atraumatic to tissue.

[0032] Figs. 13A and 13B views of a variation of lower extension members which may be configured to be actuatable.

[0033] Fig. 13C show a top view of a lower extension member which may be configured into a "C" shape.

[0034] Figs. 14A and 14B show perspective and top views of a lower extension member having one or more energize-able wires disposed thereon for tissue ablation.

[0035] Figs. 15A to 15E show side views, partially in section, of the apparatus of Figs. 14 creating and securing a tissue plication, while initiating a wound healing response.

[0036] Figs. 16A to 16C show side views of a tissue manipulation assembly which may be configured to articulate into an angle relative to the tubular body.

[0037] Figs. 17A to 17C show partial side views of variations of a handle for controlling and articulating the tissue manipulation assembly.

[0038] Figs. 18A to 18C show top, side, and cross-sectional views, respectively, of another variation of a handle having a multi-position locking and needle assembly advancement system.

[0039] Fig. 18D shows an assembly view of the handle of Fig. 18A connected to the tissue manipulation assembly via a rigid or flexible tubular body or shaft.

[0040] Figs. 19A and 19B show perspective and cross-sectional views, respectively, of another variation of a handle having a reversible configuration.

[0041] Figs. 20A and 20B show partial cross-sectional side and detail views, respectively, of another variation of a handle having a pivotable articulation control.

[0042] Fig. 21A shows a side view of the handle of Fig. 20A having the multi-position locking and needle assembly advancement system.

[0043] Figs. 21B to 21D show end views of the handle of Fig. 21A and the various positions of the multi-position locking and needle assembly advancement system.

[0044] Fig. 22A shows a perspective view of one variation of the multi-position locking and needle assembly advancement system.

[0045] Figs. 22B to 22E show illustrative side views of the system of Fig. 22A configured in various locking and advancement positions.

[0046] Fig. 23 illustrates a side view of a needle deployment assembly which may be loaded or advanced into an approximation assembly.

[0047] Fig. 24A shows a side view of one variation of a needle deployment assembly.

[0048] Fig. 24B shows an exploded assembly of Fig. 24A in which the tubular sheath is removed to reveal the anchor assembly and elongate pusher element.

[0049] Figs. 25A and 25B show partial cross-sectional side views of a shuttle element advanced within the needle assembly housing.

[0050] Figs. 26A and 26B illustrate one variation of deploying the anchors using the needle assembly.

[0051] Fig. 26C illustrates a partial cross-sectional view of one variation of the needle and anchor assemblies positioned within the launch tube.

[0052] Fig. 27 is a schematic view of apparatus comprising a medical end effector coupled to a handle via an elongate tubular body.

[0053] Fig. 28 is a side view, partially in section, of a transmission element or mechanism for transmitting force or energy to a medical end effector.

[0054] Figs. 29A and 29B are side views, partially in section, of a transmission mechanism that transmits and converts rotational motion into translation motion via a lead screw.

[0055] Figs. 30A and 30B are side views, partially in section, of a transmission mechanism that converts rotational motion into translational motion and actuates a linkage to initiate a more complex motion that actuates a tissue grasper.

[0056] Figs. 31A and 31B are side views, partially in section, of an alternative embodiment of the apparatus of Figs. 30 comprising a tissue manipulation assembly having extension members.

[0057] Figs. 32A and 32B are side views, partially in section, of a transmission mechanism that facilitates coordinated reorientation or pivoting of extension members of a tissue manipulation assembly.

[0058] Figs. 33A and 33B are side views, partially in section, of a transmission mechanism that converts hydraulic energy into mechanical energy.

[0059] Figs. 34A and 34B are side views, partially in section, of another embodiment of a hydraulically-actuated medical end effector.

[0060] Figs. 35A and 35B are, respectively, a side-sectional view and a cross-sectional view, of another hydraulically-actuated end effector.

[0061] Figs. 36A and 36B are side views, partially in section, of yet another hydraulically-actuated end effector.

[0062] Figs. 37A and 37B are side views, partially in section, of a transmission mechanism that converts electrical energy into rotational and translational mechanical energy.

[0063] Figs. 38A and 38B are side views, partially in section, of a transmission mechanism that converts electrical energy into a complex mechanical motion.

[0064] Figs. 39A and 39B are side views, partially in section, of a motor-actuated linkage.

[0065] Figs. 40A and 40B are side views, partially in section, of a transmission mechanism comprising a column of ball-bearings.

[0066] Figs. 41A and 41B are, respectively, a side-sectional view and a side-sectional detail view, of a crimping or grasping end effector actuated via a ball-bearing column transmission mechanism.

[0067] Figs. 42A and 42B are side views, partially in section, of a transmission mechanism utilizing geometric constraints.

[0068] Figs. 43A-43D are side views, partially in section, illustrating apparatus and a method for deforming a crimp with a linkage assembly actuated via a lead screw transmission mechanism.

[0069] Figs. 44A and 44B are side views, partially in section, of an alternative embodiment of the apparatus and method of Figs. 43.

[0070] Figs. 45A and 45B are side views, partially in section, of a linkage actuated via translational motion.

[0071] Fig. 46 is a schematic view of a generic transmission mechanism for transmitting force or energy to a medical end effector.

DETAILED DESCRIPTION OF THE INVENTION

[0072] In creating tissue plications, a tissue plication tool having a distal tip may be advanced (transorally, transgastrically, etc.) into the stomach. The tissue may be engaged or

grasped and the engaged tissue may be moved to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size. Examples of creating and forming tissue plications may be seen in further detail in U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

[0073] In order to first create the plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s). The tissue anchor(s) may be disposed through the muscularis and/or serosa layers of the gastrointestinal lumen.

[0074] Generally, in creating a plication through which a tissue anchor may be disposed within or through, a distal tip of a tissue plication apparatus may engage or grasp the tissue and move the engaged tissue to a proximal position relative to the tip of the device, thereby providing a substantially uniform plication of predetermined size.

[0075] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a tissue grabbing assembly end effector engages or grasps the tissue wall in its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. A tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon formation of the tissue fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

[0076] The first tissue contact area may be utilized to engage and then stretch or rotate the tissue wall over the second tissue contact area to form the tissue fold. The tissue fold then may be articulated to a position where a portion of the tissue fold overlies the second tissue contact area at an orientation that is substantially normal to the tissue fold. A tissue anchor then may be delivered across the tissue fold at or near the second tissue contact area. An apparatus which is particularly suited to deliver the anchoring and securement devices

described herein may be seen in further detail in co-pending U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which is incorporated herein by reference in its entirety.

[0077] An illustrative side view of a tissue plication assembly **10** which may be utilized with the tissue anchors described herein is shown in Fig. 1A. The plication assembly **10** generally comprises a catheter or tubular body **12** which may be configured to be sufficiently flexible for advancement into a body lumen, e.g., transorally, percutaneously, laparoscopically, etc. Tubular body **12** may be configured to be torqueable through various methods, e.g., utilizing a braided tubular construction, such that when handle **16** is manipulated and rotated by a practitioner from outside the body, the torquing force is transmitted along body **12** such that the distal end of body **12** is rotated in a corresponding manner.

[0078] Tissue manipulation assembly or end effector **14** is located at the distal end of tubular body **12** and is generally used to contact and form the tissue plication, as mentioned above. Fig. 1B shows an illustrative detail side view and Fig. 1C shows a perspective view of tissue manipulation assembly/end effector **14** which shows launch tube **18** extending from the distal end of body **12** and in-between the arms of upper extension member or bail **20**. Launch tube **18** may define launch tube opening **24** and may be pivotally connected near or at its distal end via hinge or pivot **22** to the distal end of upper bail **20**. Lower extension member or bail **26** may similarly extend from the distal end of body **12** in a longitudinal direction substantially parallel to upper bail **20**. Upper bail **20** and lower bail **26** need not be completely parallel so long as an open space between upper bail **20** and lower bail **26** is sufficiently large enough to accommodate the drawing of several layers of tissue between the two members.

[0079] Several variations of the tissue plication assembly **10** and some of the various apparatus used therewith are disclosed in further detail herein below as well as in U.S. Pat. App. Serial No. 10/954,666 filed September 29, 2004, which is incorporated herein by reference in its entirety.

[0080] Upper bail **20** is shown in the figure as an open looped member and lower bail **26** is shown as a solid member; however, this is intended to be merely illustrative and either or both members may be configured as looped or solid members. Tissue acquisition member **28** may be an elongate member, e.g., a wire, hypotube, etc., which terminates at a tissue grasper or engager **30**, in this example a helically-shaped member, configured to be reversibly

rotatable for advancement into the tissue for the purpose of grasping or acquiring a region of tissue to be formed into a plication. Tissue acquisition member **28** may extend distally from handle **16** through body **12** and distally between upper bail **20** and lower bail **26**. Acquisition member **28** may also be translatable and rotatable within body **12** such that tissue engager **30** is able to translate longitudinally between upper bail **20** and lower bail **26**. To support the longitudinal and rotational movement of acquisition member **28**, an optional guide or linear bearing **32** may be connected to upper **20** or lower bail **26** to freely slide thereon. Guide **32** may also be slidably connected to acquisition member **28**, such that guide **32** supports the longitudinal motion of acquisition member **28**.

[0081] An example of a tissue plication procedure is seen in Figs. 2A to 2D for delivering and placing a tissue anchor and is disclosed in further detail in co-pending U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated by reference above. Tissue manipulation assembly **14**, as seen in Fig. 2A, may be advanced into a body lumen such as the stomach and positioned adjacent to a region of tissue wall **40** to be plicated. During advancement, launch tube **18** may be configured in a delivery profile such that tube **18** is disposed within or between the arms of upper bail **20** to present a relatively small profile.

[0082] Once tissue manipulation assembly **14** has been desirably positioned relative to tissue wall **40**, tissue grasper or engager **30** may be advanced distally such that tissue grasper or engager **30** comes into contact with tissue wall **40** at acquisition location or point **42**. As tissue grasper or engager **30** is distally advanced relative to body **12**, guide **32**, if utilized, may slide distally along with tissue grasper or engager **30** to aid in stabilizing the grasper. If a helically-shaped tissue grasper or engager **30** is utilized, as illustrated in Fig. 2B, it may be rotated from its proximal end at handle **16** and advanced distally until the tissue at point **42** has been firmly engaged by tissue grasper or engager **30**. This may require advancement of tissue grasper or engager **30** through the mucosal layer and at least into or through the underlying muscularis layer and possibly into or through the serosa layer.

[0083] The grasped tissue may then be pulled proximally between upper **20** and lower bails **26** via tissue grasper or engager **30** such that the acquired tissue is drawn into a tissue fold **44**, as seen in Fig. 2C. As tissue grasper or engager **30** is withdrawn proximally relative to body **12**, guide **32** may also slide proximally to aid in stabilizing the device especially when drawing the tissue fold **44**.

[0084] Once the tissue fold **44** has been formed, launch tube **18** may be advanced from its proximal end at handle **16** such that a portion **46** of launch tube **18**, which extends distally from body **12**, is forced to rotate at hinge or pivot **22** and reconfigure itself such that portion **46** forms a curved or arcuate shape that positions launch tube opening **24** perpendicularly relative to a longitudinal axis of body **12** and/or bail members **20**, **26**. Launch tube **18**, or at least portion **46** of launch tube **18**, is preferably fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending. Alternatively, assembly **14** may be configured such that launch tube **18** is reconfigured simultaneously with the proximal withdrawal of tissue grasper or engager **30** and acquired tissue **44**.

[0085] As discussed above, the tissue wall of a body lumen, such as the stomach, typically comprises an inner mucosal layer, connective tissue, the muscularis layer and the serosa layer. To obtain a durable purchase, e.g., in performing a stomach reduction procedure, the staples or anchors used to achieve reduction of the body lumen are preferably engaged at least through or at the muscularis tissue layer, and more preferably, the serosa layer. Advantageously, stretching of tissue fold **44** between bail members **20**, **26** permits an anchor to be ejected through both the muscularis and serosa layers, thus enabling durable gastrointestinal tissue approximation.

[0086] As shown in Fig. 2D, once launch tube opening **24** has been desirably positioned relative to the tissue fold **44**, needle assembly **48** may be advanced through launch tube **18** via manipulation from its proximal end at handle **16** to pierce preferably through a dual serosa layer through tissue fold **44**. Needle assembly **48** is preferably a hollow tubular needle through which one or several tissue anchors may be delivered through and ejected from in securing the tissue fold **44**, as further described below.

[0087] Because needle assembly **48** penetrates the tissue wall twice, it exits within the body lumen, thus reducing the potential for injury to surrounding organs. A detail cross-sectional view is shown in Fig. 3A of anchor delivery assembly **50** in proximity to tissue fold **F**. In this example, tissue fold **F** may comprise a plication of tissue created using the apparatus described herein or any other tool configured to create such a tissue plication. Tissue fold **F** may be disposed within a gastrointestinal lumen, such as the stomach, where tissue wall **W** may define the outer or serosal layer of the stomach. Anchor delivery assembly may generally comprise launch tube **18** and needle assembly **48** slidingly disposed within launch

tube lumen **52**. Needle assembly **48** is generally comprised of needle **54**, which is preferably a hollow needle having a tapered or sharpened distal end to facilitate its travel into and/or through the tissue. Other parts of the assembly, such as upper and lower bail members **20**, **26**, respectively, and tissue acquisition member **28** have been omitted from these figures only for clarity.

[0088] Once launch tube **18** has been desirably positioned with respect to tissue fold **F**, needle **54** may be urged or pushed into or through tissue fold **F** via delivery push tube or catheter **64** from its proximal end preferably located within handle **16**. Delivery push tube or catheter **64** may comprise an elongate flexible tubular member to which needle **54** is connected or attached via joint **62**. Alternatively, needle **54** and delivery push tube **64** may be integrally formed from a singular tubular member. Needle **54** may define needle lumen **56** through which basket anchor assembly **66**, i.e., distal anchor **58** and/or proximal anchor **60** may be situated during deployment and positioning of the assembly. A single suture or flexible element **76** (or multiple suture elements) may connect proximal anchor **60** and distal anchor **58** to one another. For instance, element **76** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, biocompatible metal wire, such as Nitinol, stainless steel, Titanium, etc.

[0089] The proximal end of suture **76** may pass slidingly through proximal anchor **60** to terminate in a suture loop. The proximal end of suture **76** may terminate proximally of the apparatus **10** within control handle **16**, proximally of control handle **16**, or at some point distally of control handle **16**. In this variation, a suture loop may be provided to allow for a grasping or hooking tool to temporarily hold the suture loop for facilitating the cinching of proximal **60** and distal **58** anchors towards one another for retaining a configuration of tissue fold **F**, as described in further detail in U.S. Pat. App. Serial No. 10/840,950, which has been incorporated by reference above.

[0090] After needle assembly **48** has been pushed distally out through launch tube opening **24** and penetrated into and/or through tissue fold **F**, as shown in Fig. 3A, anchor pushrod or member **78** may be actuated also via its proximal end to eject distal anchor **58**. Once distal anchor **58** has been ejected distally of tissue fold **F**, needle **54** may be retracted back through tissue fold **F** by either retracting needle **54** back within launch tube lumen **18** or by withdrawing the entire anchor delivery assembly **50** proximally relative to tissue fold **F**.

[0091] Once needle **54** has been retracted, proximal anchor **60** may then be ejected from launch tube **18** on a proximal side of tissue fold **F**. With both anchors **58**, **60** disposed externally of launch tube **18** and suture **76** connecting the two, proximal anchor **60** may be urged into contact against tissue fold **F**, as shown in Fig. 3B. As proximal anchor **60** is urged against tissue fold **F**, proximal anchor **60** or a portion of suture **76** may be configured to provide any number of directionally translatable locking mechanisms which provide for movement of an anchor along suture **76** in a first direction and preferably locks, inhibits, or prevents the reverse movement of the anchor back along suture **76**. In other alternatives, the anchors may simply be delivered through various elongate hollow tubular members, e.g., a catheter, trocars, etc.

[0092] The basket anchors may comprise various configurations suitable for implantation within a body lumen. Basket anchors are preferably reconfigurable from a low profile delivery configuration to a radially expanded deployment configuration in which a number of struts, arms, or mesh elements may radially extend once released from launch tube **18** or needle **54**. Materials having shape memory or superelastic characteristics or which are biased to reconfigure when unconstrained are preferably used, e.g., spring stainless steels, Ni-Ti alloys such as Nitinol, etc. In Figs. 3A and 3B, each of the basket anchor **58**, **60** is illustrated as having a number of reconfigurable struts or arm members **72** extending between distal collar **68** and proximal collar **70**; however, this is intended only to be illustrative and suitable basket anchors are not intended to be limited to baskets only having struts or arms. Examples of suitable anchors are further described in detail in U.S. Pat. App. Serial No. 10/612,170, which has already been incorporated herein above.

[0093] Fig. 3B shows distal basket anchor **58** delivered through tissue fold **F** via needle **54** and launch tube **18**. As above, the other parts of the plication assembly, such as upper and lower bail members **20**, **26**, respectively, and tissue acquisition member **28** have been omitted from these figures only for clarity.

[0094] Fig. 3B shows one variation where a single fold **F** may be secured between proximal anchor **60** and distal anchor **58'**. As seen, basket anchor **58'** has been urged or ejected from needle **54** and is shown in its radially expanded profile for placement against the tissue surface. In such a case, a terminal end of suture **76** may be anchored within the distal collar of anchor **58'** and routed through tissue fold **F** and through, or at least partially through, proximal anchor **60**, where suture **76** may be cinched or locked proximally of,

within, or at proximal anchor **60** via any number of cinching mechanisms. Proximal anchor **60** is also shown in a radially expanded profile contacting tissue fold **F** along tissue contact region **74**. Locking or cinching of suture **76** proximally of proximal anchor **60** enables the adequate securement of tissue fold **F**.

[0095] Various examples of cinching devices and methods which may be utilized with the tools and devices herein are described in further detail in U.S. Pat. App. Serial No. 10/840,950 filed May 7, 2004, which has been incorporated herein above.

[0096] If additional tissue folds are plicated for securement, distal basket anchor **58** may be disposed distally of at least one additional tissue fold **F'**, as shown in Fig. 3B, while proximal anchor **60** may be disposed proximally of tissue fold **F**. As above, suture **76** may be similarly affixed within distal anchor **58** and routed through proximal anchor **60**, where suture **76** may be cinched or locked via proximal anchor **60**, as necessary. If tissue folds **F** and **F'** are to be positioned into apposition with one another, distal basket anchor **58** and proximal anchor **60** may be approximated towards one another. As described above, proximal anchor **60** is preferably configured to allow suture **76** to pass freely therethrough during the anchor approximation. However, proximal anchor **60** is also preferably configured to prevent or inhibit the reverse translation of suture **76** through proximal anchor **60** by enabling uni-directional travel of anchor **60** over suture **76**. This cinching feature thereby allows for the automated locking of anchors **58, 60** relative to one another during anchor approximation.

[0097] With respect to the anchor assemblies described herein, the types of anchors shown and described are intended to be illustrative and are not limited to the variations shown. For instance, several of the tissue anchor variations are shown as "T"-type anchors while other variations are shown as reconfigurable "basket"-type anchors, which may generally comprise a number of configurable struts or legs extending between at least two collars or support members. Other variations of these or other types of anchors are also contemplated for use in an anchor assembly. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. Furthermore, the different types of cinching or locking mechanisms are not intended to be limited to any of the particular variations shown and described but may be utilized in any of the combinations or varying types of anchors as practicable.

[0098] The upper and/or lower extension members or bails may also be configured into a variety of embodiments, which may be utilized in any number of combinations with any of

the tissue acquisition member variations as practicable. Although the upper and lower extension members or bails may be maintained rigidly relative to one another, the upper and/or lower extension members may be alternatively configured to articulate from a closed to an open configuration or conversely from an open to a closed configuration for facilitating manipulation or stabilization of tissue drawn between the bail members.

[0099] In operation, once the selected region of tissue has been acquired by the tissue grasper **30**, the obtained tissue may be proximally withdrawn between the bail members, which may act as stabilizers for the tissue. To accommodate large portions of grasped tissue between the bail members, one or both bail members may be articulated or urged to open apart from one another to allow the tissue to enter and become positioned between the bail members. One or both bail members may then be articulated or urged to clamp or squeeze the tissue fold between the bail members to facilitate stabilization of the tissue fold for tissue manipulation and/or anchor deployment and/or any other procedure to be undertaken.

[0100] One such articulatable extension assembly may be seen in the side views of Figs. 4A and 4B. Other features such as the launch tube and tubular body have been omitted merely for the sake of clarity for the following illustrations. As seen in Fig. 4A, upper extension member **182** and lower extension member **184** of active extension assembly **180** may be configured to have an open or spread configuration relative to one another when guide or linear bearing **186** is positioned distally along upper extension member **182**. Linear bearing **186** may be configured to slide freely along upper extension member **182** when urged by acquisition member **28** distally or proximally. Rather than having linear bearing **186** slide along upper extension member **182**, it may be configured alternatively to slide along lower extension member **184**.

[0101] With tissue grasper **30** and acquisition member **28** distally protruding from extension members **182, 184**, as shown in Fig. 4A, the desired region of tissue may be acquired by rotating tissue grasper **30** into the tissue. Once tissue has been acquired by tissue grasper **30**, the tissue may be pulled between the opened extension members **182, 184** by proximally withdrawing tissue grasper **30** and linear bearing **186** may be forced proximally over upper extension member **182**, as shown in the detail view of Fig. 4C. One or more projections or pistons **188** may protrude proximally from linear bearing **186** such that one or more of these projections **188** comes into contact with actuation lever or member **192**, as shown in Fig. 4D, which may be located proximally of extension members **182, 184** and

connected in a pivoting relationship with lower extension member **184** about pivot **190**. As linear bearing **186** is urged proximally and projection **188** presses against actuation lever **192**, lower extension member **184** may be rotated about pivot **190** such that lower extension member **184** is urged towards upper extension member **182** to securely clamp onto and retain any tissue positioned between the extension members **182, 184**.

[0102] Another articulatable extension assembly may be seen in assembly **200** in the side views of Figs. 5A and 5B. In this variation, upper extension member **202** may project distally opposite lower extension member **204** which may be biased to close towards upper extension member **202**. When tissue grasper **30** is advanced to engage tissue, as shown in Fig. 5A, linear bearing **206** may be urged distally along upper extension member **202** via acquisition member **28** such that lower extension member **204** is forced or wedged away from upper extension member **202**. Once the tissue is engaged and withdrawn proximally, linear bearing **206** may be pulled proximally while sliding along lower member **204** and allowing lower member **204** to spring back towards upper member **202** and over any tissue positioned therebetween, as shown in Fig. 5B.

[0103] Another articulatable extension assembly is shown in the side views of extension assembly **210** of Figs. 6A and 6B. In this variation, upper extension member **212** and/or lower extension member **214** may be connected to linkage assembly **218** located proximally of the extension members **212, 214**. Linkage assembly **218** may be manipulated via any number of control mechanisms such as control wires to urge extension members **212, 214** between open and closed configurations. Alternatively, linkage assembly **218** may be configured to open or close upon the proximal or distal advancement of linear bearing **216** relative to linkage assembly.

[0104] Figs. 7A to 7C show side views of another variation in extension assembly **220** where upper and lower extension members **222, 224** are articulatable between open and closed configurations via a pivoting arm or member **234** interconnecting the two. In this example, a first end of pivoting arm **234** may be in a pivoting connection at pivot **228** with linear bearing **226**, which may slide translationally along upper member **222**. A second end of pivoting arm **234** may also be in a pivoting connection with lower extension member **224** at pivot **230**, which may remain fixed to lower member **224**. Acquisition member **28** may also be in a third pivoting connection with pivoting arm **234** at pivot **232**, which may also be configured to allow for the linear translation of acquisition member therethrough.

[0105] In operation, when acquisition member **28** and tissue grasper **30** is advanced distally, as shown in Fig. 7A, both upper and lower extension members **222**, **224** are in a closed configuration with linear bearing **226** being advanced distally along upper extension member **222**. As tissue grasper **30** is withdrawn proximally between extension members **222**, **224**, pivoting arm **234** may be pivoted about fixed pivot **230** on lower member **224** while upper member **222** is urged into an open configuration as linear bearing **226** is urged proximally over upper member **222**, as shown in Fig. 7B. This expanded or open configuration allows for the positioning of large portions of tissue to be drawn between the extension members **222**, **224** for stabilization. Fig. 7C shows tissue grasper **30** as having been further withdrawn and linear bearing **226** urged proximally such that upper member **222** is urged back into a closed configuration relative to lower member **224**. The closing of extension members **222**, **224** allows for the members to further clamp upon any tissue therebetween for further stabilization of the tissue.

[0106] Figs. 8A and 8B show another alternative in active extension assembly **240**. In this variation, upper extension member **242** may be biased to extend away from lower extension member **244**. As shown in Fig. 8A, upper extension member **242** may remain in an open configuration relative to lower member **244** for receiving tissue therebetween. In this variation, biased upper member **242** may be urged into a closed configuration by pivoting the launch tube **18** about pivot **246**, which may be located along upper member **242**. As launch tube **18** is pivoted into an anchor deployment configuration, the pivoting action may urge upper member **242** towards lower member **244** to clamp upon any tissue therebetween.

[0107] Figs. 9A and 9B show yet another alternative in assembly **250** where upper extension member **252** and/or lower extension member **254** may be passively urged into an open configuration. In this example, lower extension member **254** is shown as being flexed from a relaxed configuration in Fig. 9A to a flexed configuration in Fig. 9B. As linear bearing **256** is withdrawn proximally, any tissue engaged to tissue grasper **30** may urge lower extension member **254** from its normal position **258** to its flexed and opened position. Accordingly, lower extension member **254** and/or upper extension member **252** may be made from a relatively flexible plastic or metallic material, e.g., Nitinol, spring stainless steel, etc. When tissue is removed from between the extension members **252**, **254**, lower extension member **254** may return to its normal configuration **258**.

[0108] Figs. 10A and 10B show side views of another assembly **260** in which upper and/or lower extension members **262, 264** may be biased or configured to flex away from one another, as shown in Fig. 10A. Once linear bearing **266** and tissue grasper **30** has been retracted, an outer sleeve **268** slidingly disposed over tubular body **12** may be pushed distally such that sleeve **268** is slid over at least a proximal portion of extension members **262, 264** such that they are urged towards one another into a closed configuration onto tissue which may be present therebetween, as shown in Fig. 10B.

[0109] Aside from features such as articulation of the extension members, the extension members themselves may be modified. For instance, Fig. 11 shows a side view of extension assembly **270** where lower extension member **274** may be extended in length relative to upper extension member **272**. The length of lower extension member **274** may be varied depending upon the desired result. Alternatively, upper extension member **272** may be shortened relative to lower extension member **274**. The lengthening of lower extension member **274** may be utilized to present a more stable platform for tissue approximated between the extension members **262, 264**.

[0110] Another alternative for modifying the extension members is seen in the side view of Fig. 12 in extension assembly **280**. In this example, one or both extension members **282, 284** may be configured to have atraumatic blunted ends **286** which may be further configured to be flexible to allow tissue to slide over the ends. Moreover, atraumatic ends **286** may be configured in a variety of ways provided that an atraumatic surface or feature is presented to the tissue.

[0111] In addition to atraumatic features, the lower extension member of the tissue manipulation assembly may be varied as well. For example, as the needle assembly and tissue anchors are deployed from the launch tube, typically from the upper extension member, it is preferable to have sufficient clearance with respect to the lower extension member so that unhindered deployment is facilitated. One method for ensuring unhindered deployment is via a lower extension member having a split opening defined near or at its distal end, as shown in the perspective view of tissue manipulation assembly **290** in Fig. 13A. Such a split may allow for any deployed anchors or suture an opening through which to be released from assembly **290**.

[0112] Additionally, the jaws that define the opening may be articulatable as well relative to lower extension member **294**. As shown in the bottom view of Fig. 13B, articulatable

lower extension assembly **292** may have one or both jaw members **296, 298** articulatable via pivots **300, 302**, respectively, relative to lower extension member **294** such that one or both jaw members **296, 298** are able to be moved between a closed configuration, as shown in Fig. 13A, and an open configuration, as shown in Fig. 13B. This variation in assembly **290** may allow for any needle or anchor assemblies to easily clear lower extension member **294**.

[0113] Another variation of lower extension member **304** is shown in the bottom view of Fig. 13C. In this variation, an enclosing jaw member **306** may extend from lower extension member **304** such that an opening **308** along either side of extension member **304** is created. Such an opening **308** may create a "C"-shaped lower extension member **304** which may facilitate needle and anchor deployment from the tissue manipulation assembly.

[0114] Another variation of a tissue manipulation assembly **310** may be seen in the illustrative partial perspective view of Fig. 14A. In addition to articulation or release features, one or both extension members may be utilized to selectively ablate regions of tissue. Assembly **310** for instance may have a tissue ablation assembly **312** integrated into the lower extension member **320**. Such a tissue ablation assembly **312**, as seen in the top view of Fig. 14B, may incorporate one or more wires or electrically conductive elements **318** upon lower extension member **320** to create a tissue ablation region. The lower extension member **320** may be fabricated from a non-conductive material upon which wires **318** may be integrated. Alternatively, the entire lower member **320** may be electrically conductive with regions selectively insulated leaving non-insulated areas to create ablation regions **318**. The wires or regions **318** may be electrically connected via wires **314** to power source **316**, which may provide various forms of energy for tissue ablation, e.g., radio-frequency, microwave, etc.

[0115] One example for use of the ablative tissue manipulation assembly may be seen in Figs. 15A to 15E where tissue approximation assembly **330** may be seen with tissue manipulation assembly **14** advanced through an optional shape-lockable overtube **332**. Ablation region **318** is integrated into the lower extension member **320** of the tissue manipulation assembly, as above. Alternatively, region **318** may, for example, comprise an abrasive surface disposed on lower extension member **320**. Alternatively, the lower extension member **320** may comprise an ablation electrode for injuring mucosal tissue.

[0116] As seen in Fig. 15B, when tissue wall **40** is folded between the extension members of assembly **14**, target mucosal tissue **334** contacts lower extension member **320** as well as

ablation region **318**. Passive or active actuation of ablation region **318** may then injure and/or remove the target mucosal tissue **334**. As further seen in Fig. 15C, this procedure may be repeated at one or more additional tissue folds **336, 338** that may then be approximated together, as in Fig. 15D. The contacting injured regions of mucosal tissue promote healing and fusion **340** of the approximated folds, as in Fig. 15E.

[0117] Aside from variations on aspects of the tissue manipulation assembly, the entire assembly may also be modified to adjust the tissue manipulation assembly position relative to the tubular body upon which the assembly is attachable. Fig. 16A shows a distal portion of tubular body **12** and tissue manipulation assembly **14** connected thereto. While tubular body **12** may comprise a rigid or flexible length, tissue manipulation assembly **14** may be further configured to articulate relative to tubular body **12**, as shown in Fig. 16B, to further enhance the maneuverability and manipulation capabilities of tissue manipulation assembly **14**. In one example, assembly **14** may be connected to tubular body **12** via a hinged or segmented articulatable portion **350**, shown in the detail Fig. 16C, which allows assembly **14** to be reconfigured from a low-profile configuration straightened relative to tubular body **12** to an articulated configuration where assembly **14** forms an angle, α, relative to tubular body **12**. The angle, α, may range anywhere from 180° to -180° depending upon the desired level of articulation. Articulatable portion **350** may be configured to allow assembly **14** to become articulated in a single plane or it may also be configured to allow a full range of motion unconstrained to a single plane relative to tubular body **12**. Articulation of assembly **14** may be accomplished any number of various methods, e.g., control wires.

[0118] The tissue manipulation assembly may be manipulated and articulated through various mechanisms. One such assembly that integrates each of the functions into a singular unit may be seen in the handle assembly **16**, which is connected via tubular body **12** to the tissue manipulation assembly. Such a handle assembly may be configured to separate from tubular body **12**, thus allowing for reusability of the handle. Moreover, such a handle may be fabricated from a variety of materials such as metals or plastics, provided that the materials are preferably biocompatible. Examples of suitable materials may include stainless steel, PTFE, Delrin®, etc.

[0119] One variation of a handle assembly **16** is shown in the illustrative side view of handle **500** in Fig. 17A with half of handle enclosure **502** removed for clarity for discussion purposes. As shown, handle enclosure **502** may connect with tubular body **12** at its distal end

at tubular interface **504**. The proximal end of handle **500** may define acquisition member opening **506** which opens to acquisition member receiving channel **508** defined through enclosure **502** from opening **506** to tubular interface **504**. The acquisition member **28** may be routed through receiving channel **508** with the proximal end **510** of acquisition member **28** extending proximally of enclosure **502** for manipulation by the user. Acquisition member proximal end **510** may further have an acquisition member rotational control **512** that the user may grasp to manipulate acquisition member **28**.

[0120] Acquisition member receiving channel **508** preferably has a diameter which is sufficiently large enough to allow for the translational and rotational movement of acquisition member through the receiving channel **508** during tissue manipulation. Acquisition member lock **524**, e.g., a screw or protrusion, may also extend at least partially into acquisition member receiving channel **508** such that lock **524** may be urged selectively against acquisition member **28** to freeze a position of acquisition member **28**, if so desired. The terminal end of receiving channel **508** may extend to tubular interface **504** such that receiving channel **508** and tubular body **12** are in communication to provide for the passage of acquisition member **28** therethrough.

[0121] In addition to the acquisition member controls, the handle enclosure **502** may also provide a needle assembly receiving channel **514** through which needle assembly control **516** and needle assembly catheter **518** may be translated through. Needle assembly receiving channel **514** may extend from needle assembly opening **520** also to tubular interface **504**. Needle assembly receiving channel **514** extends to tubular interface **504** such that needle assembly receiving channel **514** and tubular body **12** are also in communication to provide for the passage of needle assembly catheter **518** therethrough.

[0122] In operation, once the tissue to be plicated has been acquired and drawn between the lower and upper extension members by acquisition member **28**, as described above, the launch tube **18** may be advanced distally and rotated into its deployment configuration. Once positioned for deployment, the needle assembly may be advanced into and/or through the tissue by urging needle assembly control **516** and needle assembly catheter **518** distally into needle assembly receiving channel **514**, as shown by the advancement of control **516** in Fig. 17B. The tissue anchors may then be deployed from the needle assembly catheter **518** via the needle assembly control **516**, as further described below. Withdrawal of the needle assembly

from the tissue may be accomplished by the proximal withdrawal of needle assembly control **516** and assembly catheter **518**.

[0123] Tissue manipulation articulation control **522** may also be positioned on handle **500** to provide for selective articulation of the tissue manipulation assembly, as shown above in Figs. 16A to 16C. This variation shows articulation control **522** rotatably positioned on handle enclosure **502** such that articulation control **522** may be rotated relative to handle **500** to selectively control the movement of the tissue manipulation assembly. Articulation control **522** may be operably connected via one or several control wires attached between articulation control **522** and the tissue manipulation assembly. The control wires may be routed through tubular interface **504** and extend through tubular body **12**.

[0124] Fig. 17C shows another variation of handle enclosure **502** where the tissue manipulation articulation control **526** may be positioned on a side surface of handle enclosure **502**. Articulation control **526** may include a ratcheting mechanism **528** within enclosure **502** to provide for controlled articulation of the tissue manipulation assembly.

[0125] Figs. 18A to 18C show top, side, and cross-sectional views, respectively, of another variation on the handle assembly. As seen in Figs. 18A and 18B, an advancement control **530** may be adapted to selectively slide translationally and rotationally through a defined advancement channel or groove **532** defined within handle enclosure **502**. Advancement control **530** may be used to control the deployment and advancement of needle assembly control **516** as well as deployment of the launch tube, as described in further detail below.

[0126] Fig. 18D shows an assembly side view of the handle assembly, tubular body **12**, and tissue manipulation assembly and the corresponding motion of the assembly when manipulated by the handle. As described above, tissue acquisition member proximal end **510** and acquisition member control **512** may be advanced or withdrawn from the handle enclosure **502** in the direction of arrow **534** to transmit the corresponding translational motion through tubular body **12** to tissue acquisition member **28** and tissue grasper **30**, as indicated by the direction of corresponding arrow **536**. Likewise, when acquisition member control **512** is rotated relative to handle enclosure **502**, as indicated by rotational arrow **538**, the corresponding rotational motion is transmitted through tubular body **12** to tissue grasper **30** for screwing into or unscrewing from tissue, as indicated by corresponding rotational arrow **540**. As mentioned above, tubular body **12** may be rigid or flexible depending upon the application utilized for the device.

[0127] Likewise, longitudinal translation of needle assembly control **516** relative to enclosure **502**, as indicated by the arrow may transmit the corresponding longitudinal motion to the needle assembly through the launch tube when reconfigured for deployment. The tissue manipulation assembly articulation control **522** may also be seen in this handle variation as being rotatable in the direction of arrow **542** relative to handle enclosure **502**. Depending upon the direction of articulation, control **522** may be manipulated to elicit a corresponding motion from the tissue manipulation assembly about hinge or articulatable section **350** in the direction of arrows **544**.

[0128] Another handle variation may be seen in the perspective view of handle assembly **550**, as shown in Fig. 19A. This particular variation may have handle enclosure **552** formed in a tapered configuration which allows for the assembly **550** to be generally symmetrically-shaped about a longitudinal axis extending from its distal end **554** to its proximal end **556**. The symmetric feature of handle assembly **550** may allow for the handle to be easily manipulated by the user regardless of the orientation of the handle enclosure **552** during a tissue manipulation procedure. An additional feature which may further facilitate the ergonomic usability of handle assembly **550** may further include at least one opening **558** defined through the enclosure **552** to allow the user to more easily grip and control the handle **550**. Another feature may include grips **560**, **562** which may extend from either side of enclosure **552**.

[0129] As seen in the figure, acquisition member **564** may include additional features to facilitate control of the tissue. For instance, in this variation, in addition to the rotational control **566**, an additional rotational control **568** may extend proximally from control **566** and have a diameter smaller than that of control **566** for controlling fine rotational motion of acquisition member **564**.

[0130] Fig. 19B shows a side view of the handle assembly **550** of Fig. 19A with the enclosure **552** partially removed for clarity. As shown, needle assembly control **570** may be seen inserted within an additional needle deployment mechanism **576**, as described below in further detail, within needle assembly receiving channel **574**. Acquisition member **564** may also be seen positioned within acquisition member receiving channel **572**.

[0131] Yet another variation of the handle assembly may be seen in the side view of the handle assembly of Fig. 20A where the handle enclosure **522** is partially removed for clarity. In this variation, needle deployment mechanism lock **580**, e.g., a screw or protrusion, may be

configured to operably extend at least partially into needle assembly receiving channel **574** to selectively lock the launch tube and/or needle assembly control within receiving channel **574**. Also shown is acquisition member receiving channel **582** through which the acquisition member may be translated and/or rotated. Acquisition member lock **584** may also be seen to extend at least partially into the acquisition member receiving channel **582** to selectively lock the acquisition member position, if so desired. The acquisition member receiving channel **582** may be optionally threaded **586** such that the acquisition member may be advanced or withdrawn using a screw-like mechanism.

[0132] An additional needle deployment mechanism lock **594** may also be seen pivotally mounted about pivot **596** within enclosure **522**. Mechanism **594** may be biased via deployment mechanism biasing element **598**, e.g., a spring, to maintain a biasing force against mechanism **594** such that the needle assembly control may automatically become locked during advancement within enclosure **522** to allow for a more controlled anchor deployment and needle assembly advancement.

[0133] Moreover, one or more pivotable tissue manipulation assembly controls **588** may be mounted to enclosure **522** and extend from one or both sides of enclosure **522** to provide for articulation control of the tissue manipulation assembly, as described above. As presently shown in Fig. 20B in the detail side view from the handle assembly of Fig. 20A, one or more control wires **592** may be connected to control **588** at control wire attachment points **600**. Control **588** may pivot about tissue acquisition pivot **590** located within handle enclosure **522**. As control **588** is pivoted, the articulation of control wires **592** may articulate a position of the tissue manipulation assembly, as discussed above. Fig. 20B shows an example of the range of motion which may be possible for control **588** as it is rotated about pivot **590**.

[0134] Fig. 21A shows a side view of another variation of handle enclosure **610** which incorporates a needle deployment locking and advancement control **612** which is adapted to be advanced and rotated within needle deployment travel **614** into various positions corresponding to various actions. Locking control **612** may be utilized in this variation to selectively control access of the needle assembly within handle enclosure **610** as well as deployment of the needle assembly and launch tube advancement with a single mechanism. A needle assembly, such as needle assembly **570**, may be advanced into handle enclosure **610** with locking control **612** initially moved into needle assembly receiving position **616**, shown also in the end view of Fig. 21B. Once the needle assembly has been initially introduced into

enclosure **610**, the needle assembly may be locked within enclosure **610** by rotating locking control **612** into its needle assembly locking position **618**, clockwise rotation as shown in the end view of Fig. 21C. The needle assembly may be locked within enclosure **610** to prevent the accidental withdrawal of the needle assembly from the enclosure **610** or inadvertent advancement of the needle assembly into the tissue.

[0135] With locking control **612** in the needle assembly locking position **618**, the needle deployment mechanism within enclosure **610** may also be longitudinally translated in a distal direction by urging locking control **612** distally within needle deployment travel **614**. Urging locking control **612** distally translates not only the needle deployment mechanism within enclosure **610**, but may also translate the launch tube distally such that the launch tube distal portion is pivoted into its deployment configuration, as described above. As the needle deployment mechanism is distally translated within enclosure **610**, the needle assembly may also be urged distally with the deployment mechanism such that needle assembly becomes positioned within the launch tube for advancing the needle body into the tissue.

[0136] Once locking control **612** has been advanced distally, locking control **612** may again be rotated into the needle assembly release position **620**, clockwise rotation as shown in the end view of Fig. 21D. Once in the release position **620**, the needle assembly may be free to be translated distally within enclosure **610** for advancing the needle assembly and needle body relative to the launch tube and enclosure **610**. To remove the needle assembly from enclosure **610**, the steps may be reversed by moving locking control **612** proximally back to its initial needle assembly receiving position **616** so that the needle assembly is unlocked from within enclosure **610**. A new needle assembly may then be introduced into enclosure **610** and the process repeated as many times as desired.

[0137] Details of one variation of the locking mechanism disposed within the handle enclosure **610** are shown in the perspective view of Fig. 22A. The other elements of the handle assembly have been omitted from this illustration for clarity. The locking mechanism may generally be comprised of outer sleeve **630** disposed about inner sleeve **632**. Outer sleeve **630** preferably has a diameter which allows for its unhindered rotational and longitudinal movement relative to inner sleeve **632**. Needle deployment locking control **612** may extend radially from outer sleeve **630** and protrude externally from enclosure **610**, as described above, for manipulation by the user. Outer sleeve **630** may also define needle assembly travel path **636** along its length. Travel path **636** may define the path through

which needle assembly **570** may traverse in order to be deployed. Needle assembly **570** may define one or more guides **638** protruding from the surface of assembly **570** which may be configured to traverse within travel path **636**. Inner sleeve **634** may also define guides **634** protruding from the surface of inner sleeve **634** for traversal within grooves defined in handle enclosure **610**. Moreover, outer sleeve **630** is preferably disposed rotatably about inner sleeve **632** such that outer sleeve **630** and inner sleeve **632** are configured to selectively interlock with one another in a corresponding manner when locking control **612** is manipulated into specified positions.

[0138] Turning to Figs. 22B to 22E, the operation of the locking mechanism of Fig. 22A is described in further detail. As needle assembly **570** is initially introduced into handle enclosure **610** and the locking mechanism, needle assembly **570** may be rotated until guides **638** are able to slide into longitudinal receiving channel **640** of travel path **636** defined in outer sleeve **630**, as shown in Figs. 22B and 22C. Locking control **612** may be partially rotated, as described above in Figs. 21B and 21C, such that outer sleeve is rotated with respect to needle assembly **570** and guides **638** slide through transverse loading channel **642**, as shown in Fig. 22D. In this position, the locking mechanism may be advanced distally to deploy the launch tube and to also advance needle assembly **570** distally in preparation for needle assembly **570** deployment. Once the launch tube has been desirably advanced, locking control **612** may again be partially rotated, as shown in Fig. 21D, such that guides **638** on needle assembly **570** are free to then be advanced within longitudinal needle assembly channel **644** relative to the handle enclosure **610** for deploying the needle assembly **570** from the launch tube and into or through the tissue. As mentioned above, the needle assembly **570** may be removed from enclosure **610** and the locking mechanism by reversing the above procedure.

[0139] As described above, needle deployment assembly **650** may be deployed through approximation assembly **10** by introducing needle deployment assembly **650** into the handle **16** and through tubular body **12**, as shown in the assembly view of Fig. 23, such that the needle assembly **656** is advanced from the launch tube and into or through approximated tissue. Once the needle assembly **656** has been advanced through the tissue, the anchor assembly **658** may be deployed or ejected. Anchor assembly **658** is normally positioned within the distal portion of tubular sheath **654** which extends from needle assembly control or housing **652**. Once the anchor assembly **658** has been fully deployed from sheath **654**, the spent needle deployment assembly **650** may be removed from approximation assembly **10**, as

described above, and another needle deployment assembly may be introduced without having to remove assembly **10** from the patient. The length of sheath **654** is such that it may be passed entirely through the length of tubular body **12** to enable the deployment of needle assembly **656** into and/or through the tissue.

[0140] Fig. 24A shows a detailed assembly view of the needle deployment assembly **650** from Fig. 23. In this variation, elongate and flexible sheath or catheter **654** may extend removably from needle assembly control or housing **652**. Sheath or catheter **654** and housing **652** may be interconnected via interlock **660** which may be adapted to allow for the securement as well as the rapid release of sheath **654** from housing **652** through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. Needle body **662**, which may be configured into any one of the variations described above, may extend from the distal end of sheath **654** while maintaining communication between the lumen of sheath **654** and needle opening **664**.

[0141] Elongate pusher **666** may comprise a flexible wire or hypotube which is translationally disposed within sheath **654** and movably connected within housing **652**. A proximally-located actuation member **668** may be rotatably or otherwise connected to housing **652** to selectively actuate the translational movement of elongate pusher **666** relative to sheath **654** for deploying the anchors from needle opening **664**. Anchor assembly **658** may be seen positioned distally of elongate pusher **666** within sheath **654** for deployment from sheath **654**. Needle assembly guides **670** may also be seen protruding from housing **652** for guidance through the locking mechanism described above. Fig. 24B shows an exploded assembly view of the needle deployment assembly **650** from Fig. 24A. As seen, sheath **654** may be disconnected from housing **652** via interlock **660** to reveal the elongate pusher **666** connected to housing **652** and the distal and proximal anchors **58**, **60**, respectively, of anchor assembly **658**.

[0142] Figs. 25A and 25B show partial cross-sectional views of one variation of housing **652**. As shown in fig. 25A, elongate pusher **666** may be attached to shuttle **682**, which in turn may be connected to threaded interface element **686**. As actuation member **668** is manipulated, e.g., by rotating it clockwise, lead screw **684** may be rotated about its longitudinal axis to advance threaded interface element **686** over lead screw **684** distally through shuttle channel **680**, as shown in Fig. 25B, where shuttle **682** has been advanced entirely through shuttle channel **680**. Tubular sheath interlock **688** may be seen at the distal

portion of housing **652** through which the elongate pusher **666** may be advanced. To reverse the direction of elongate pusher **666** and shuttle **682**, actuation member **668** may be reversed in the opposite direction.

[0143] Another variation of the needle deployment assembly may be seen in Figs. 26A and 26B which show assembly side views. In this variation, housing **652** may define an indicator window **690** along the length of housing **652** to enable viewing of a visual indicator **692** which may be utilized to indicate the position of the elongate pusher **666** within the sheath **654**. In the illustration of Fig. 26A, as actuation member **668** is manipulated to advance pusher **666** distally, indicator **692** may move correspondingly within window **690**. Positional indicators may also be marked along window **690** to indicate to the user when specified limits have been reached. For instance, positional indicator **694** may be marked such that alignment of indicator **692** with positional indicator **694** is indicative to the user that distal anchor **58** has been deployed from sheath **654**.

[0144] Likewise, an additional positional indicator **696** may be marked such that alignment of indicator **692** with positional indicator **694** is indicative to the user that the proximal anchor **60** has also been deployed from sheath **654**, as shown in Fig. 26B. Any number of positional indicators or methods for visually marking may be utilized as the above examples are merely intended to be illustrative and not limiting. Moreover, to further facilitate the visualization of anchor positioning within sheath **654**, the sheath itself may be fabricated from a transparent material, such as plastics, so that the user may visually locate a position of one or both anchors during anchor deployment into or through the tissue.

[0145] Fig. 26C shows an illustrative cross-sectional view of the launch tube **18** in its deployment configuration. Tubular sheath **654** and needle body **662** may be seen positioned within the distal portion of launch tube **18** ready for deployment into any tissue (not shown for clarity) which may be positioned between upper and lower extension members **20, 26**. Also shown are distal and proximal anchors **58, 60**, respectively (suture is not shown for clarity), positioned within sheath **654** distally of elongate pusher **666**.

[0146] Various force transmission elements or configurations may be provided to actuate elements of end effectors. Such end effectors may, for example, comprise previous described end effector **14**, or any alternative medical end effector. Referring to Fig. 27, an embodiment of apparatus **10** is provided comprising flexible tubular body **12** that couples end effector **14**

to handle **500**. Force transmission elements, such as those described previously and/or those described hereinafter, optionally may be integrated into, and/or actuable via, the handle.

[0147] With reference to Fig. 28, a first embodiment of such a force transmission element illustratively is shown actuating a tissue acquisition member that may, for example, be utilized as part of end effector **14** of apparatus **10**. As will be apparent, the force transmission element (as with other force transmission elements described hereinafter) optionally may be utilized to actuate other elements of end effector **14** of apparatus **10**, or of some other medical end effector. Tissue acquisition member **700** comprises elongated member **710** disposed within outer sheath **720**. Outer sheath **720** optionally may comprise locally necked-down distal region **722** that acts as a bearing surface for rotation and/or translation of elongated member **710**. Elongated member **710** comprises distal tissue grasper **712**, illustratively a helical tissue grasper. As illustrated by arrows in Fig. 28, rotation of a proximal region of member **710** transmits a rotational torque to distal tissue grasper **712**. Likewise, translation of the proximal region translates the grasper. Member **710** optionally may be translationally (or rotationally) fixed relative to outer sheath **720**, e.g., fixed at necked down distal region **722** of the outer sheath. It should be understood that outer sheath **720** optionally may comprise the working channel of an endoscope or other medical instrument, *per se* known.

[0148] Referring now to Figs. 29, a force transmission element that transmits and converts rotational motion into translation motion via a lead screw mechanism is described. In Figs. 29, tissue acquisition member **700** comprises elongated member **710'** having distal lead screw **714**. Tissue grasper **712'** comprises mating screw **716**. As seen in Fig. 29A, rotation of a proximal region of member **710'** in a first direction translationally advances tissue grasper **712'** relative to outer sheath **720** via the lead screw coaction of distal screw **714** of elongated member **710'** with mating screw **716** of tissue grasper **712'**. Likewise, as seen in Fig. 29B, rotation of the proximal region of member **710'** in the opposite direction actuates the lead screw to translationally retract grasper **712'** relative to outer sheath **720**.

[0149] With reference to Figs. 30, tissue acquisition member **700** converts rotational motion into translational motion that actuates a linkage to initiate a more complex motion. In Figs. 30, the male and female elements of the lead screw have been reversed. Specifically, tissue grasper **730** comprises member **732** having male screw **714**, while elongated member **710'** comprises female mating screw **716**. It should be understood that the screw elements may be reversed, as desired.

[0150] Tissue grasper **730** may further comprise four bar linkage **734** having first and second bars **735a** and **735b**, respectively, that are coupled at pivot **740** to member **732**. The four bar linkage further comprises third and fourth bars **736a** and **736b**, respectively, that are coupled to the first and second bars at pivots **742a** and **742b**, respectively. The third and fourth bars cross and are pivotally attached to one another, as well as to sheath **720**, at pivot **744**. First and second jaw members **738a** and **738b** extend from (or are integrally formed with) the third and fourth bars, respectively, for grasping tissue.

[0151] As seen in Fig. 30A, rotation of a proximal region of member **710'** in a first direction translationally advances member **732** of tissue grasper **730** relative to sheath **720** and/or elongated member **710'** via the coacting lead screw. Advancement of member **732** actuates four bar linkage **734** in a manner that separates and opens jaw members **738a** and **738b**, e.g., for engaging or releasing engaged tissue. As seen in Fig. 30B, rotation of member **710'** in an opposite direction translationally retracts member **732** of grasper **730** relative to sheath **720**/member **710'**. This actuates four bar linkage **734** in a manner that approximates and closes jaw members **738**, e.g., to secure engaged tissue therebetween or to provide a lower profile delivery or retrieval configuration.

[0152] Referring to Figs. 31, an alternative embodiment of the apparatus of Figs. 30 is described. In Figs. 31, tissue acquisition member **700** comprises tissue manipulation assembly **730'** rather than tissue grasper **730**. Specifically, jaw members **738** of grasper **730** have been replaced with first and second extension members **738'**. First extension member **738a'** may extend from third bar **736a** of four bar linkage **734**, while second extension member **738b'** may likewise extend from second bar **735b** of the linkage. As seen in Figs. 31, rotation of member **710'** advances or retracts member **732**, which actuates four bar linkage **734** and reorients the extension members relative to sheath **720**.

[0153] In the embodiment of Figs. 31, a separation distance between the extension members may vary during actuation of linkage **734** and reorientation of the extension members. Figs. 32 provide apparatus and a method for coordinated reorientation or pivoting of extension members of a tissue manipulation assembly, whereby the separation distance between the extension members does not vary. Apparatus **800** comprises sheath **810** having first and second guide lumens **812a** and **812b**, respectively, disposed within the wall of the sheath. Elongated members **820a** and **820b** having first and second lead screws **822a** and **822b**, respectively, are disposed within guide lumens **812**. Extension members **830** are

integrally formed into a U-shaped structure that is connected to gear **840** at attachment **832**. Attachment **832** may pivotably attach the gear and extension members to sheath **810**. Gear **840** comprises teeth **842** that are configured to coact with lead screws **822**.

[0154] As illustrated by arrows in Fig. 32B, coordinated rotation of elongated members **820a** and **820b** in opposing directions pivots or reorients extension members **830** relative to sheath **810** via coaction of gear teeth **842** with lead screws **822**. As will be apparent, extension members **830** alternatively may be reoriented via coaction of gear **840** with a single lead screw **822**. Furthermore, a medical practitioner may actively rotate only a single elongated member **820**, and the secondary elongated member **820** may passively rotate in an opposing direction via interaction of its lead screw with the gear. Furtherstill, the first and second elongated members **820** may be rotated in the same direction, or one of the elongated members may be held stationary while the other is rotated, in order to friction lock an orientation or position of extension members **830** relative to sheath **810**.

[0155] Referring now to Figs. 33, hydraulic rotation of extension members **830** is described. In Figs. 33, extension members **830** are coupled to fluid wheel or turbine **850**. Fluid wheel **850** comprises multiple extensions or spokes **852** that facilitate hydraulic rotation of the wheel. The fluid wheel and extension members **830** may be pivotably attached to sheath **860** at pivot **862**. Sheath **860** comprises fluid channel **864** having fluid **F** disposed therein. Spokes **852** of fluid wheel **850** communicate with channel **864**. As illustrated by arrows in Fig. 33B, fluid **F** may be forced through channel **864** under pressure to apply a hydraulic moment to spokes **852** of wheel **850** that rotates the wheel about pivot **862** in the direction of fluid flow. Rotation of wheel **850** rotates and reorients extension members **830** that are attached to the wheel relative to sheath **860**.

[0156] With reference to Figs. 34, independent hydraulic rotation of each of the extension members is described. Extension members **870a** and **870b** comprise fluid wheels **872a** and **872b**, respectively, having spokes **874a** and **874b**, respectively. Wheels **872a** and **872b** are pivotably coupled to sheath **860** at pivots **876a** and **876b**, respectively, which are disposed in fluid channel **864** of sheath **860**. Pressurized flow of fluid **F** through channel **864** applies hydraulic moments to spokes **874a** and **874b** of the fluid wheels that rotate the wheels about pivots **876** in the direction of fluid flow. Rotation of wheels **872a** and **872b** independently rotates and reorients extension members **870a** and **870b** relative to sheath **860**.

[0157] Referring now to Figs. 35, hydraulic actuation of a tissue acquisition member or tissue grasper is described. Helical tissue grasper **880** comprises shaft **882** having propeller **884** disposed within fluid channel **864** of sheath **860**. Helical grasper **880** is configured for rotation within extension **866** of sheath **860**. Pressurized flow of fluid **F** through channel **864** rotates propeller **884**, which in turns rotates helical tissue grasper **880**. Fluid **F** may, for example, flow through channel **864** in a first direction to rotate helical grasper **880** in a direction appropriate for engaging tissue, and may flow in an opposing direction to rotate the helical grasper in an opposing direction appropriate for disengaging the tissue.

[0158] With reference to Figs. 36, fluid wheel or gear **890** having spokes or teeth **892** is pivotably coupled to sheath **860** at pivot **894** disposed within channel **864**. Helical grasper **900** comprises shaft **902** having proximal corrugations or protrusions **904** that are configured to coact with teeth **892** of fluid gear **890**. As illustrated in Fig. 36B, pressurized flow of fluid **F** in a first direction through channel **864** applies a moment to teeth **892** of gear **890** that rotates the gear about pivot **894**. This rotation advances helical grasper **900** relative to sheath **860** via coaction of teeth **892** of gear **890** with corrugations **904** of shaft **902** of grasper **900**. Fluid flow through channel **864** in an opposing direction would retract grasper **900** relative to sheath **860** in a similar fashion.

[0159] Referring now to Figs. 37, motor-actuated force transmission elements for advancing and rotating an end effector element are described. Helical tissue acquisition member or grasper **950** comprises shaft **952** that is proximally coupled to drive shaft **962** of first electric motor **960**. Motor **960** is slidably disposed within sheath **980** and comprises mating screw **964** that is configured to coact with lead screw drive shaft **972** of second electric motor **970**. Second motor **970** is coupled to sheath **980**. First motor **960** comprises positive and negative electrical hook-ups **966**, while second motor **970** comprises electrical hook-ups **976**.

[0160] A current passed through first motor **960** via electrical hook-ups **966** rotates the motor's drive shaft **962**, which rotates helical grasper **950**. Reversing the polarity of current passed through motor **960** reverses the direction of rotation of grasper **950**. Passage of a current through second motor **970** via electrical hook-ups **976** rotates lead screw drive shaft **972**, which coacts with mating screw **964** of first motor **960** to advance or retract the first motor relative to sheath **980**, thereby advancing or retracting helical tissue grasper **950** relative to the sheath.

[0161] With reference to Figs. 38, a motor-actuated jaw tissue grasper is described. Tissue grasper **1000** comprises first and second jaws **1002a** and **1002b**, respectively, having interdigitating distal teeth **1004** for engaging tissue. Jaws **1002** further comprise proximal gears **1006** having teeth **1008** that are configured to coact with lead screw drive shaft **1012** of electric motor **1010**. Gears **1006** are pivotably connected to sheath **1016** at pivots **1007**. Motor **1010**, which is coupled to sheath **1016**, comprises electrical hook-ups **1014**, and passage of an electrical current through the motor via the hookups rotates lead screw drive shaft **1012**. Coaction of gear teeth **1008** with the rotating lead screw acts to approximate or separate first and second jaws **1002**, depending on the polarity of the current passed through the motor.

[0162] Referring to Figs. 39, a motor-actuated four-bar linkage is described. Linkage **1020** comprises first and second bars **1022a** and **1022b**, respectively, that are coupled at pivot **1032** to nut member **1030**. The four bar linkage further comprises third and fourth bars **1024a** and **1024b**, respectively, that are coupled to the first and second bars at pivots **1026a** and **1026b**, respectively. The third and fourth bars cross and are pivotably attached to one another, as well as to sheath **1040**, at pivot **1042**. Sheath **1040** comprises through-holes, side-ports or windows (not shown) that accommodate expansion of four bar linkage **1020**.

[0163] Nut member **1030** is concentrically disposed about, and comprises a mating screw adapted to coact with, lead screw drive shaft **1052** of electric motor **1050**. Motor **1050** is coupled to sheath **1040**, and it comprises electrical hook-ups **1054**. Passage of an electrical current through the motor via the hook-ups rotates lead screw drive shaft **1052**, which advances or retracts nut member **1030** relative to the drive shaft, dependent on the direction of rotation of the drive shaft. As seen in Fig. 39B, advancement of the nut member actuates linkage **1020** in a manner that shortens and expands the linkage.

[0164] Referring now to Figs. 40, a force transmission element comprising a column of ball-bearings is described. The apparatus of Figs. 40 is substantially the same as the apparatus of Figs. 33, except that channel **864** of sheath **860** is filled with collinearly-aligned ball-bearings **1100**, rather than fluid **F**. As illustrated by arrows in Fig. 40B, the column of ball-bearings **1100** may be pushed through channel **864** to apply a moment to spokes **852** of wheel **850** that rotates the wheel about pivot **862** in the direction of motion of the ball-bearing column. Rotation of wheel **850** rotates and reorients extension members **830** that are attached to the wheel relative to sheath **860**.

[0165] With reference now to Figs. 41, crimping or grasping via a ball-bearing column is described. Crimping jaws **1200a** and **1200b** are pivotably connected to one another and to sheath **1210** at pivot **1212**. Each crimping jaw comprises a distal crimping surface **1202** and a proximal mating screw **1204**. The proximal mating screws are coaxially disposed over rod **1220** having first and second oppositely-turned lead screws **1222a** and **1222b** that are configured to coact with mating screws **1204**. Rod **1220** is rotatably coupled to sheath **1210**, and rotation of the rod causes crimping jaws **1200a** and **1200b** to move in opposite directions (either towards one another or away from one another) via the lead screws. The previously described column of ball-bearings **1100** is also provided, either with a channel of sheath **1210** or within their own malleable sleeve. The column of ball-bearings extends around and contacts a central region of rod **1220**.

[0166] As seen in the detail view of Fig. 41, the central region of rod **1220** comprises profiled surface **1224** having multiple divots configured for placement of a ball bearing therein. In this manner, ball-bearing column **1100** engagingly contacts rod **1220**, such that movement of the column rotates the rod. As mentioned, such rotation opens or closes jaws **1200**, dependent upon the direction of rotation. Jaws **1200** may, for example, be spread apart for placement of a crimp therebetween, then approximated to deform the crimp. Such crimping may be controlled from a proximal location by a medical practitioner via the column of ball-bearings.

[0167] Referring now to Figs. 42, a force transmission mechanism utilizing geometric constraints is described. Grasper or crimper **1300** comprises jaws **1302a** and **1302b** that are pivotably joined at pivot **1304** and are biased into a spread or open configuration, e.g. via a spring. Proximal extension **1306** extends from pivot **1304**, and wire **1308** extends proximally from extension **1306**. Wire **1308** extends through tube **1310**. Grasper **1300** is disposed within sheath **1320** having conical or wedge-shaped distal insert **1322** through which proximal extension **1306** of the grasper extends.

[0168] Jaws **1302** of grasper **1300** may be advanced out of sheath **1320** by advancing tube **1310** against extension **1306** of the grasper. Such advancement of the grasper may be achieved by a medical practitioner advancing a proximal portion of the tube disposed outside of a patient. As seen in Fig. 42A, jaws **1302** spread apart to their biased, open configuration. The jaws then may be approximated, e.g., to engage tissue or deform a crimp, by retracting

wire **1308** from outside the patient, such that the jaws contact distal insert **1322** of sheath **1320** and are urged together into an approximated configuration, as in Fig. 42B.

[0169] Referring now to Figs. 43, a method of deforming a crimp with a linkage assembly is described. The apparatus of Figs. 43 is similar to that of Figs. 39. Previously-described linkage **1020** is proximally coupled at pivot **1032** to nut member **1030**, and is distally coupled at pivot **1042** to sheath **1400**. Nut member **1030** is concentrically disposed about, and comprises a mating screw adapted to coact with, lead screw **1412** of elongated member **1410**. Extension member **1420** is coupled to nut member **1030** and is slidably disposed within linear bearings **1402** of sheath **1400**. Rotation of elongated member **1410** advances or retracts nut member **1030** along the lead screw, which, in turn, advances or retracts extension member **1420** and expands or collapses linkage **1020**.

[0170] As seen in Fig. 43A, a distal end of sheath **1400** may be disposed in proximity to crimp **1500** having suture **S** running therethough. In Fig. 43B, the crimp may be disposed within open chamber **1404** of the sheath and may be deformed by rotating elongated member **1410** to actuate the lead screw, which expands linkage **1020** and urges member **1420** against the crimp. Linkage **1020** then may be collapsed, and member **1420** may be moved proximally, by rotating elongated member **1410** in the opposite direction to actuate the lead screw in a manner that retracts nut member **1030** relative to sheath **1400**. As seen in Fig. 43C, deformed crimp **1500** then may be removed from chamber **1404**. Thereafter, the deformed crimp will maintain the position of suture **S** relative to the crimp. As seen in the detail view of Fig. 43D, a similar deformation mechanism may be achieved with a two bar embodiment of linkage **1020**, as well as with the top portion of chamber **1404** and/or at least one of the linear bearings **1402** removed.

[0171] With reference to Figs. 44, an alternative embodiment of the apparatus and method of Figs. 43 is described. As seen in Figs. 43B and 43C, linkage **1020** may be used to form a single kink in crimp **1500**. However, multiple linkages may be provided to form multiple kinks in the crimp. It is expected that providing multiple kinks in the crimp will produce a more tortuous path through the crimp, e.g., a more tortuous path for passage of suture **S** through crimp **1500** that will better maintain the position of the suture relative to the crimp.

[0172] In Figs. 44, first and second linkages **1020a** and **1020b** illustratively are provided to form first and second kinks or bends in crimp **1500**. First and second elongated members **1410** having first and second lead screws **1412** are also provided. As illustrated in Figs. 44,

the linkages may be coupled to extension member 1420, or may move independently along the lead screws via nut members **1030**. As seen in Fig. 44A, crimp **1500** may be disposed between linkages **1020a** and **1020b**. The linkages then may be expanded to deform the crimp with multiple kinks or bends, as in Fig. 44B.

[0173] Referring now to Fig. 45, a four-bar linkage actuated via linear or translational motion is described. Linkage **1020'** is similar to linkage **1020** and comprises first and second bars **1022a** and **1022b**, respectively, that are coupled at pivot **1032** to piston member **1030'**. The four bar linkage further comprises third and fourth bars **1024a** and **1024b**, respectively, that are coupled to the first and second bars at pivots **1026a** and **1026b**, respectively. The third and fourth bars cross and are pivotably attached to one another, as well as to sheath **1040**, at pivot **1042**. Sheath **1040** comprises through-holes, side-ports or windows (not shown) that accommodate expansion of four bar linkage **1020'**.

[0174] Piston member **1030'** is coupled to push-pull member **1600**, which extends through sheath **1040** to a proximal region, where it may be manipulated by a medical practitioner. As seen in Fig. 45B, advancement of push-pull member **1600** relative to sheath **1040** advances piston member **1030'**, which in turn actuates linkage **1020'** in a manner that shortens and expands the linkage. Subsequent retraction of member **1600** relative to the sheath retracts the piston member, which elongates and collapses the linkage back to the delivery configuration of Fig. 45A. As will be apparent, jaw members or graspers, extension members, or any other end effector may be coupled to, and/or actuated by, linkage **1020'**.

[0175] A variety of transmission mechanisms have been described for transmitting force, energy and/or power along desired vectors over significant distances from a medical practitioner to an end effector. It should be understood that the embodiments are provided for illustration only, and elements of the embodiments may be used in any combination as practicable. Fig. 46 provides a schematic representation for a generic transmission mechanism. A medical practitioner positioned at location **A** transmits force, energy and/or power to an end effector disposed at position **B**. The direction or type of the force/power/energy may be converted at or in the vicinity of position **B** to a form or direction appropriate for actuating the end effector. For example, force may be converted from rotational to translational, or vice versa. Additionally or alternatively, energy may be converted from electrical or fluid to mechanical, etc.

[0176] A variety of mechanisms, *per se* known, may be utilized to transmit force/power/energy from the medical practitioner to the end effector. These include, but are not limited to, hydraulic pumps; fluid compressors; pressure tanks; condensate separators and drain valves; compressed air systems, regulators or valves; hydraulic cylinders; electromechanical and/or linear actuators and solenoids; electric or air motors; speed reducers; roller chains; sprockets and bushings; clutches and torque limiters; timing and drive belts or pulleys; linear, rotational, plain, ball, tapered, needle, thrust or mounted bearings; lead screws; ball screws; linear motion; track or drive rollers; screw jacks; turntables; shaft collars or couplings; universal joints; rod ends and linkages; clevises; control cables; gas springs; shock absorbers; encoders; pistons; etc. Additional known mechanisms will be apparent to those of skill in the art.

[0177] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Moreover, although specific configurations and applications may be shown, it is intended that the various features may be utilized in various types of procedures in various combinations as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. Apparatus for conveying force or energy to a medical end effector, the apparatus comprising:

an elongate member having a proximal end and a distal end, and a length therebetween, the medical end effector positioned at the distal end of the elongate member; and

a transmission mechanism configured to transfer force or energy between the proximal end of the elongate member and the medical end effector,

wherein the transmission mechanism is configured to alter the direction or form of the force or energy as it is transferred between the proximal end of the elongate member and the medical end effector, and

wherein the medical end effector is configured to fold tissue.

2. The apparatus of claim 1, wherein the transmission mechanism is configured to alter translational force or energy into rotational force or energy.

3. The apparatus of claim 1, wherein the transmission mechanism configured to alter rotational force or energy into translational force or energy.

4. The apparatus of claim 1, wherein the transmission mechanism configured to alter hydraulic force or energy into mechanical force or energy.

5. The apparatus of claim 1, wherein the transmission mechanism comprises a lead screw.

6. The apparatus of claim 1, wherein the transmission mechanism comprises a column of ball-bearings.

7. The apparatus of claim 1, wherein the medical end effector comprises a tissue acquisition member.

8. The apparatus of claim 1, wherein the medical end effector comprises a tissue engagement member.

9. The apparatus of claim 1, wherein the medical end effector comprises a tissue grasper.

10. The apparatus of claim 1, wherein the medical end effector comprises a tissue securement element for securing folded tissue.

11. The apparatus of claim 1, wherein the medical end effector comprises a crimping element.

12. The apparatus of claim 1, wherein the medical end effector comprises a tissue manipulation assembly having extension members for folding tissue therebetween.

13. The apparatus of claim 1, wherein the medical end effector comprises a linkage.

14. The apparatus of claim 1, wherein the medical end effector comprises a gear.

15. The apparatus of claim 1, wherein the medical end effector comprises a turbine.

16. The apparatus of claim 1, wherein the elongate member is flexible, and wherein the apparatus is configured for endoluminal placement of the end effector within a patient.

17. The apparatus of claim 1, wherein the apparatus is configured for laparoscopic placement of the end effector within a patient.

18. A method for performing a medical procedure with a medical end effector disposed at a distal end of an elongate member, the method comprising:

advancing the medical end effector into a patient;

transmitting force or energy to the medical end effector from a proximal region of the elongate member disposed outside the patient;

altering the force or energy as it is transmitted to the medical end effector, and

performing the medical procedure with the end effector via the altered force or energy,

wherein performing the medical procedure comprises folding tissue.

19. The method of claim 18, wherein advancing the medical end effector into a patient further comprises endoluminally advancing the end effector into the patient.

20. The method of claim 18, wherein advancing the medical end effector into a patient further comprises laparoscopically advancing the end effector into the patient.

21. The method of claim 18, wherein altering the force or energy further comprises altering the direction or form of the force or energy.

22. The method of claim 18, wherein altering the force or energy comprises the altering the force or energy from translational to rotational force or energy.

23. The method of claim 18, wherein altering the force or energy comprises the altering the force or energy from rotational to translational force or energy.

24. The method of claim 18, wherein altering the force or energy comprises the altering the force or energy from hydraulic to mechanical force or energy.

25. The method of claim 18 wherein performing the medical procedure further comprises securing the folded tissue.

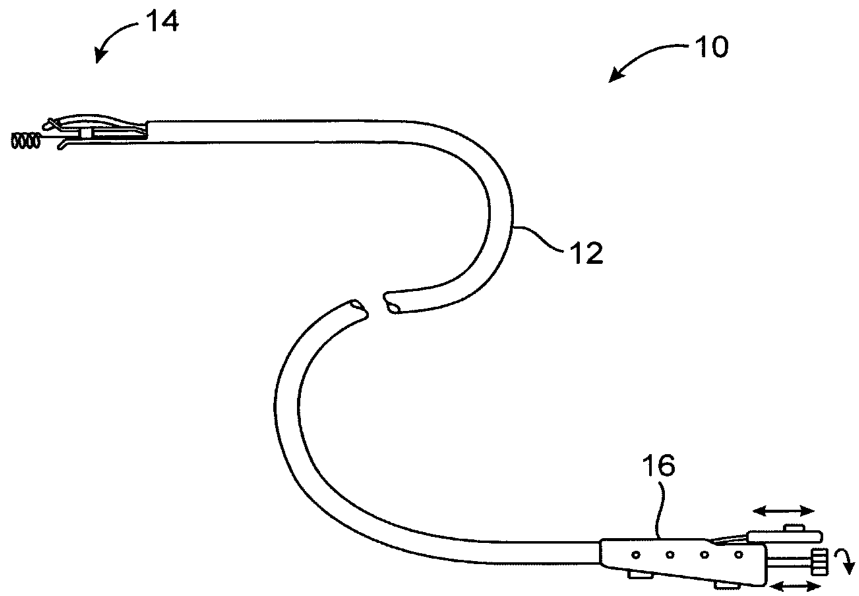

FIG. 1A

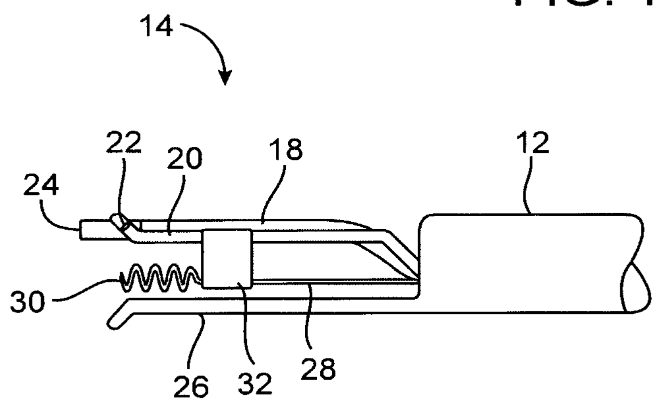

FIG. 1B

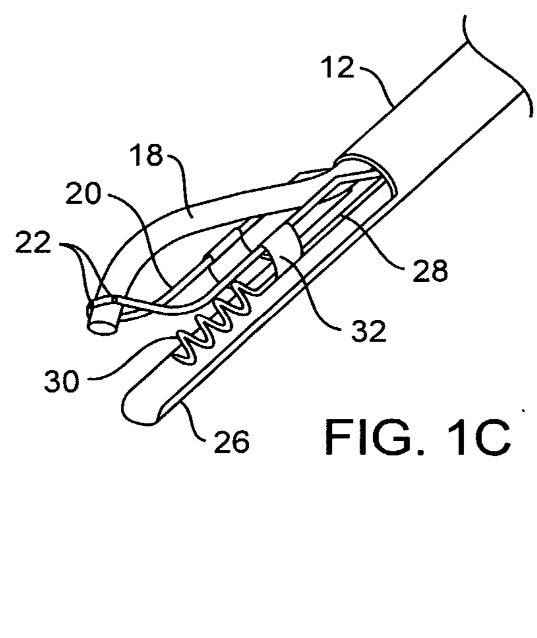

FIG. 1C

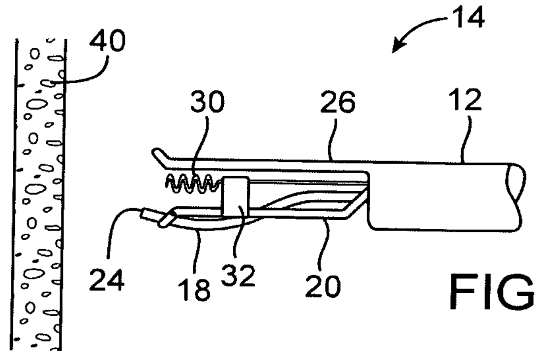

FIG. 2A

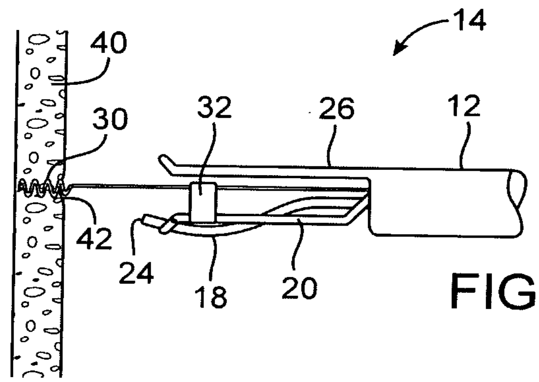

FIG. 2B

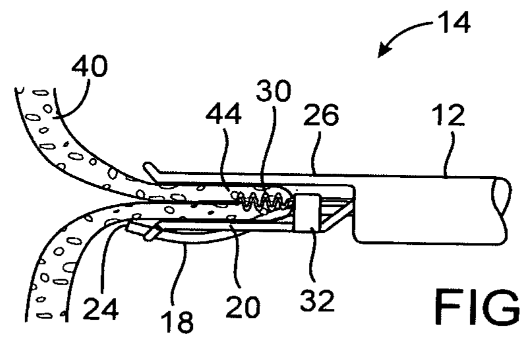

FIG. 2C

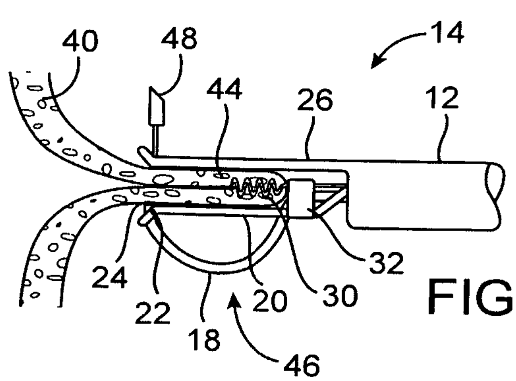

FIG. 2D

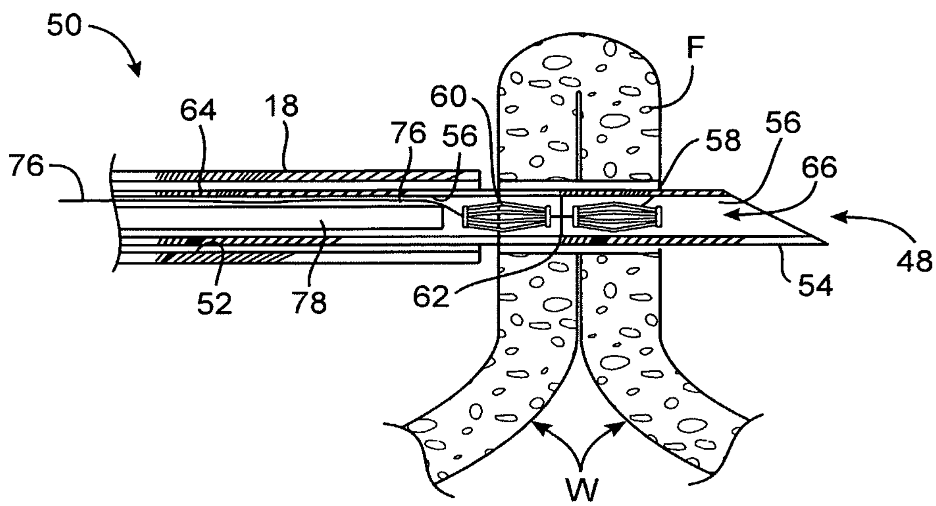
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FIG. 3A

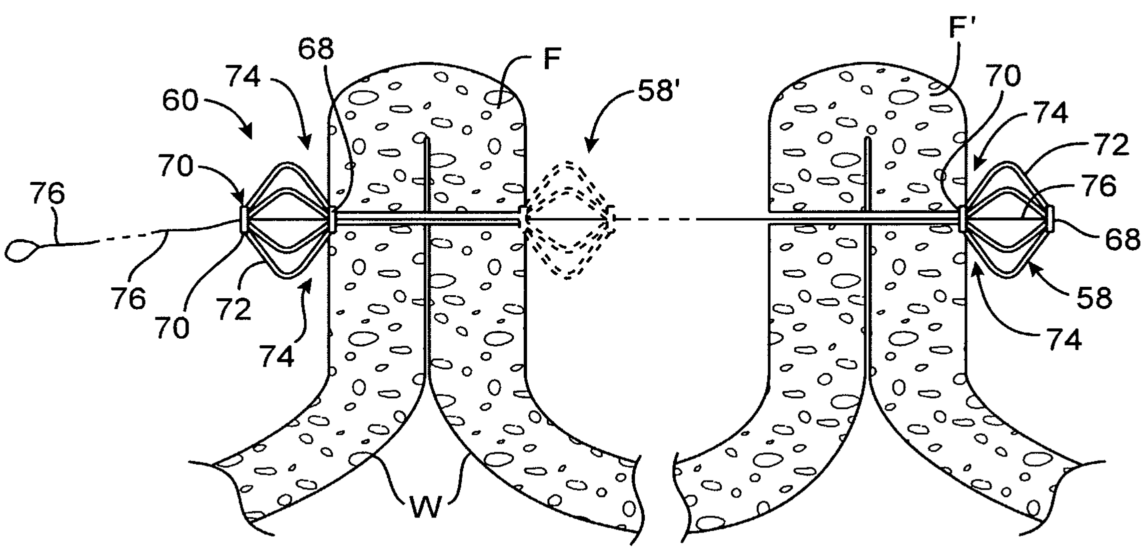
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FIG. 3B

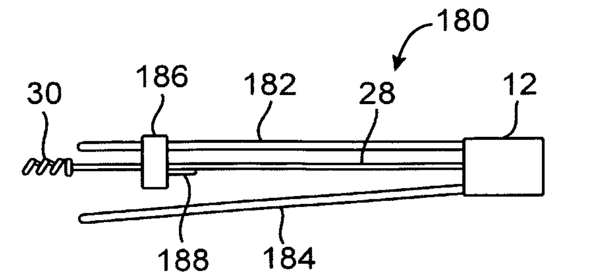

FIG. 4A

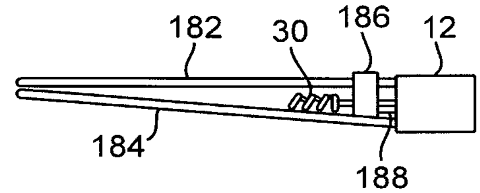

FIG. 4B

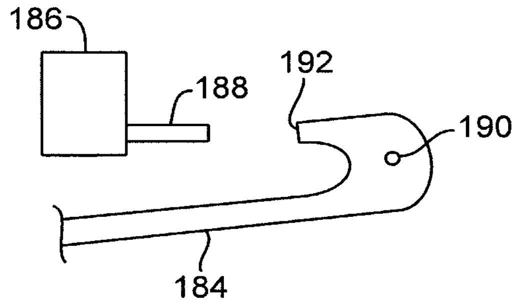

FIG. 4C

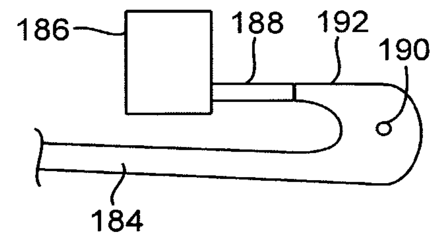

FIG. 4D

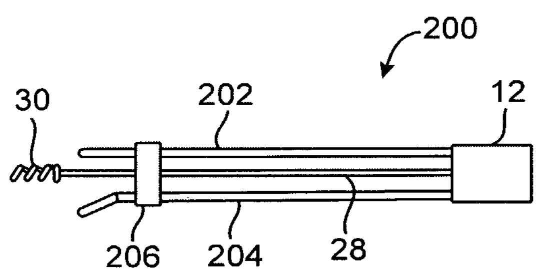

FIG. 5A

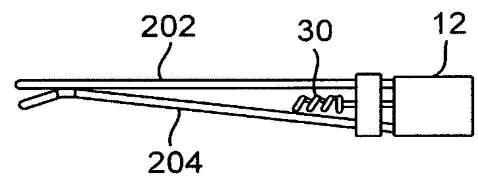

FIG. 5B

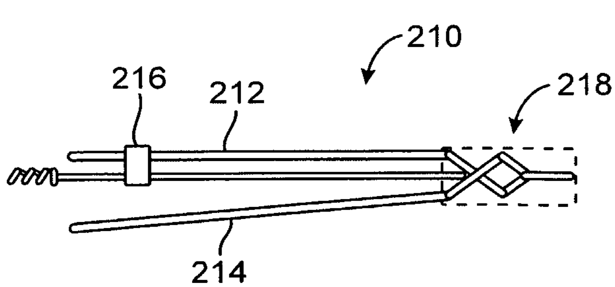

FIG. 6A

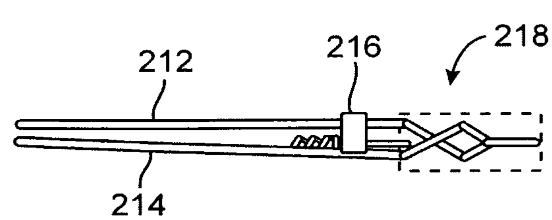

FIG. 6B

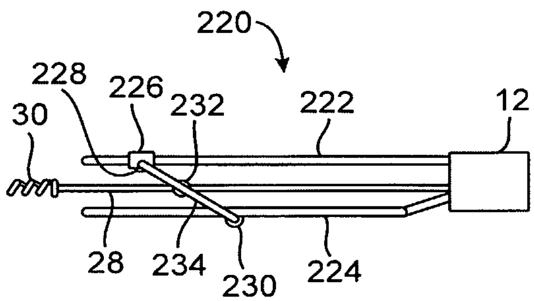

FIG. 7A

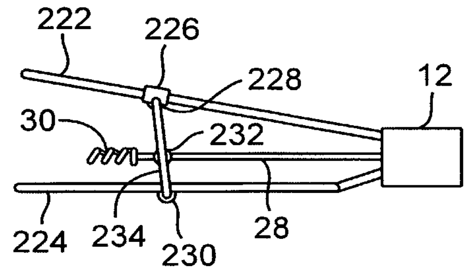

FIG. 7B

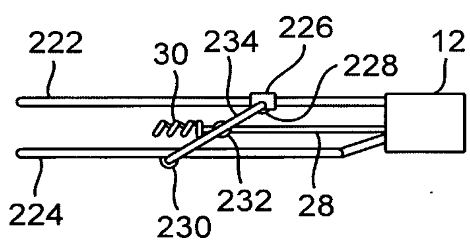

FIG. 7C

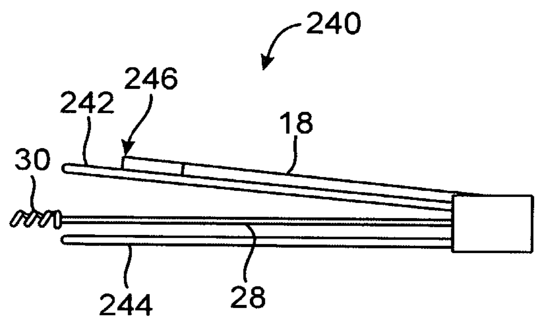

FIG. 8A

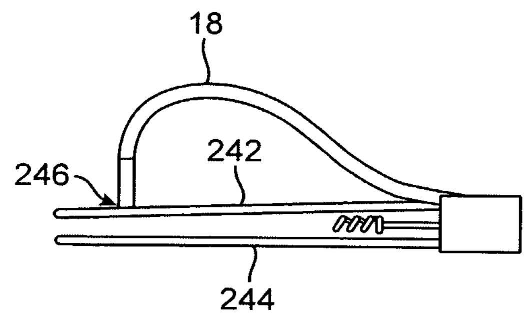

FIG. 8B

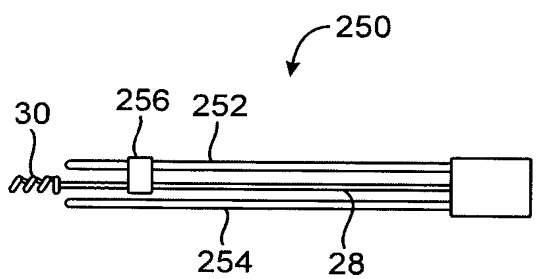

FIG. 9A

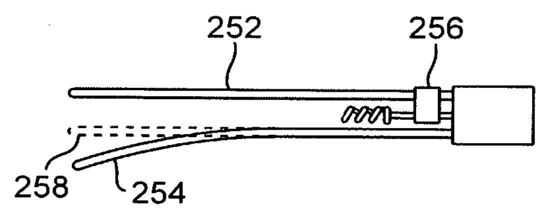

FIG. 9B

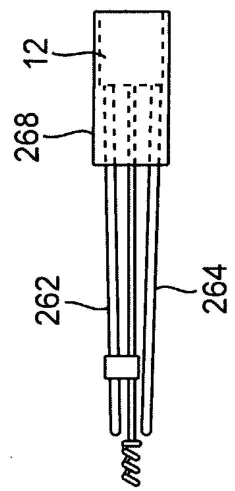

FIG. 10B

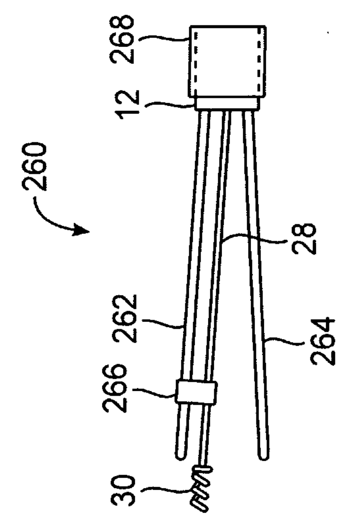

FIG. 10A

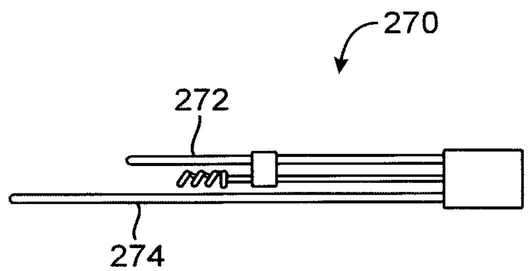

FIG. 11

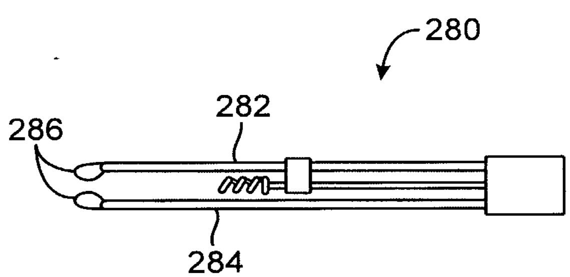

FIG. 12

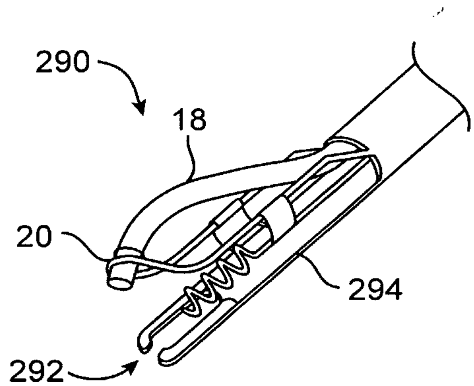

FIG. 13A

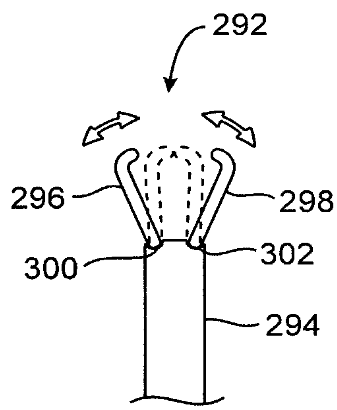

FIG. 13B

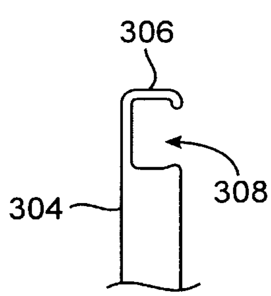

FIG. 13C

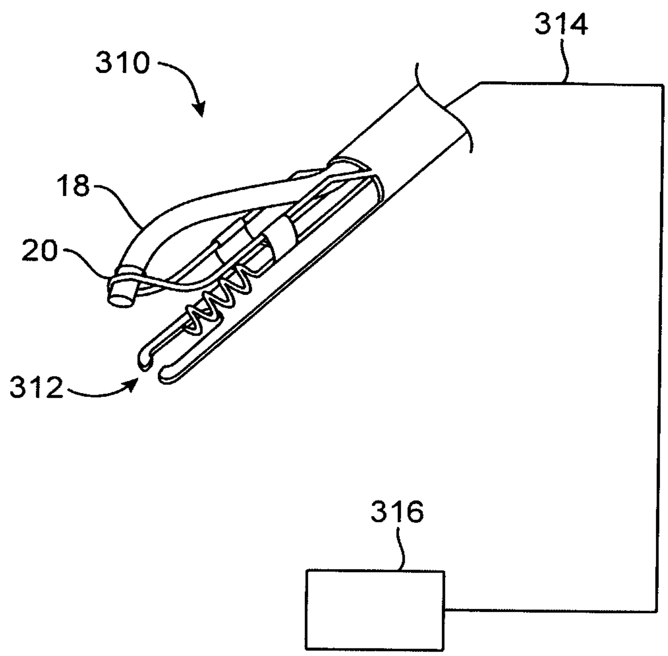

FIG. 14A

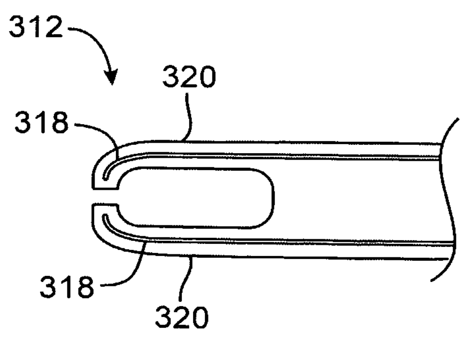

FIG. 14B

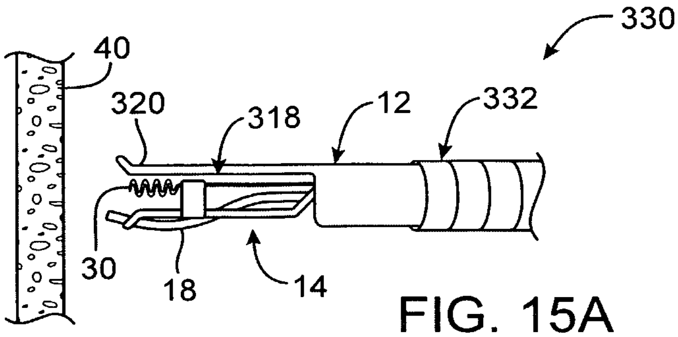

FIG. 15A

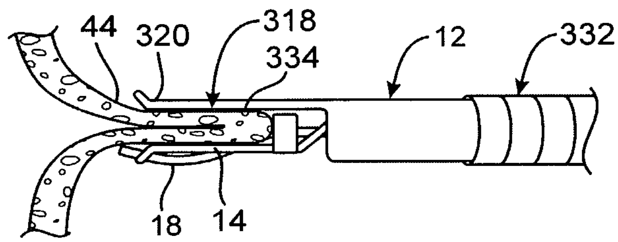

FIG. 15B

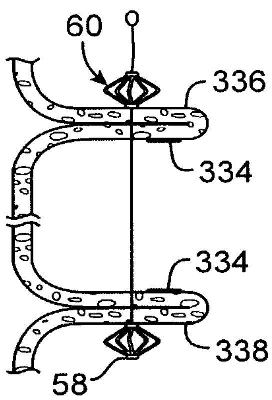

FIG. 15C

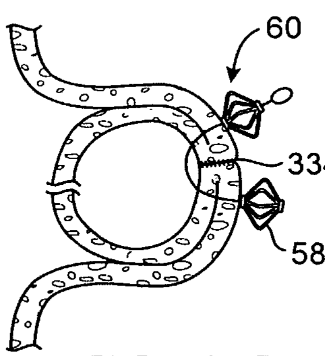

FIG. 15D

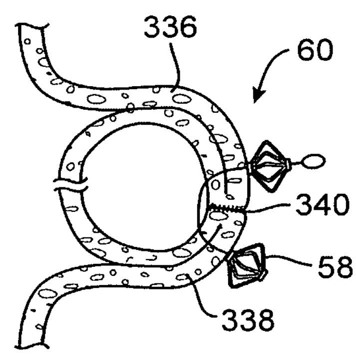

FIG. 15E

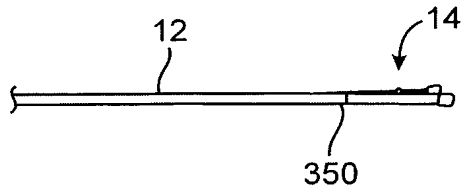

FIG. 16A

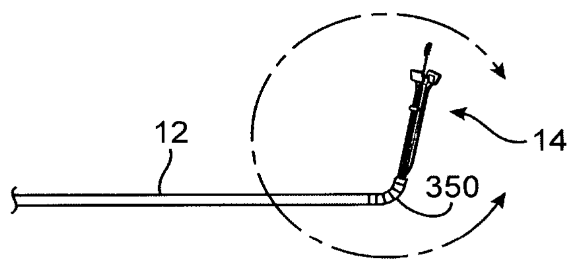

FIG. 16B

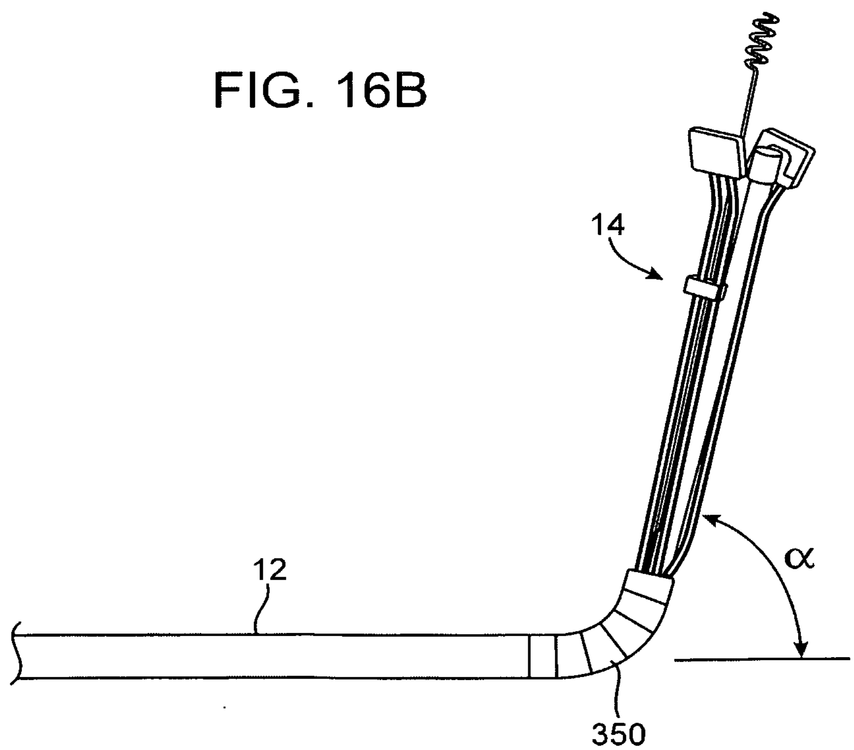

FIG. 16C

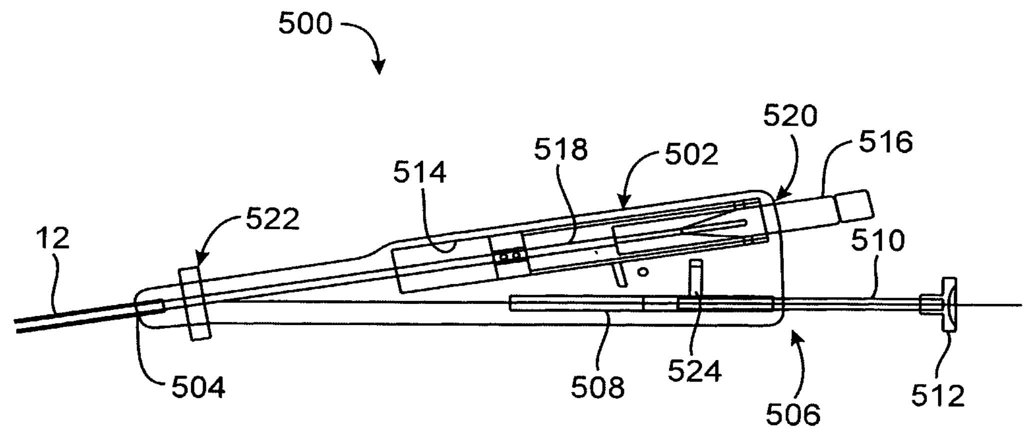

FIG. 17A

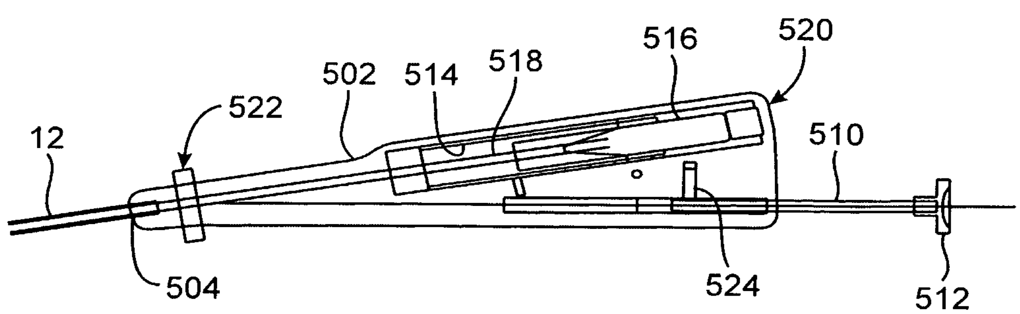

FIG. 17B

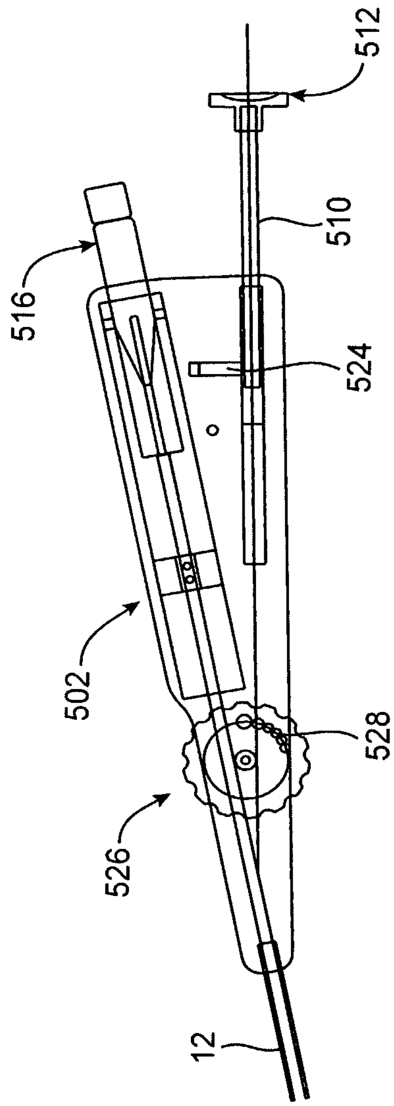

FIG. 17C

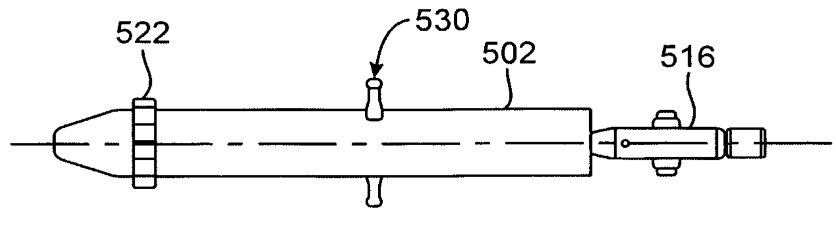

FIG.18A

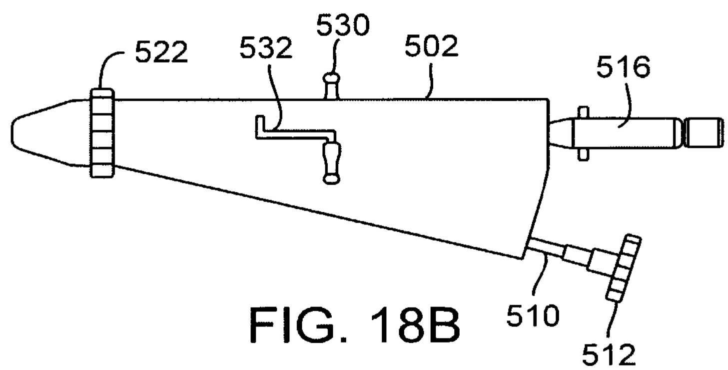

FIG. 18B

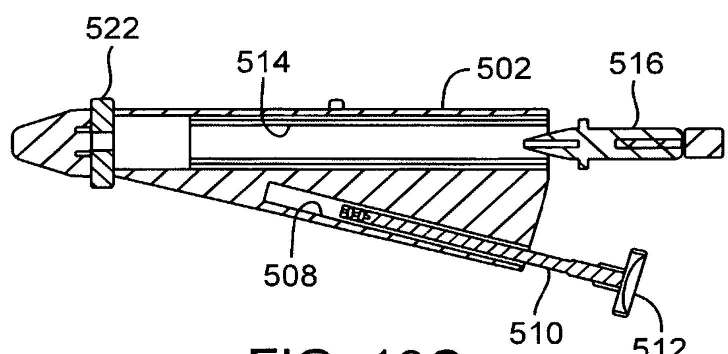

FIG. 18C

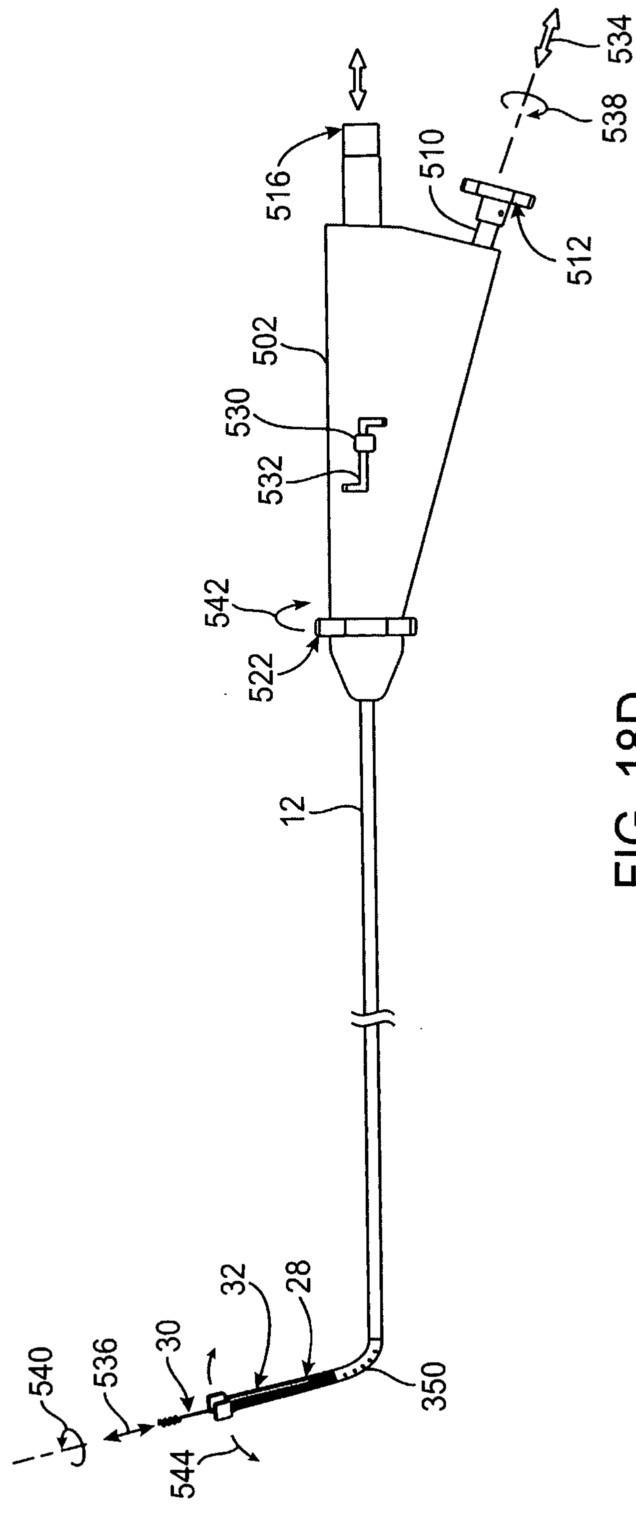
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FIG. 18D

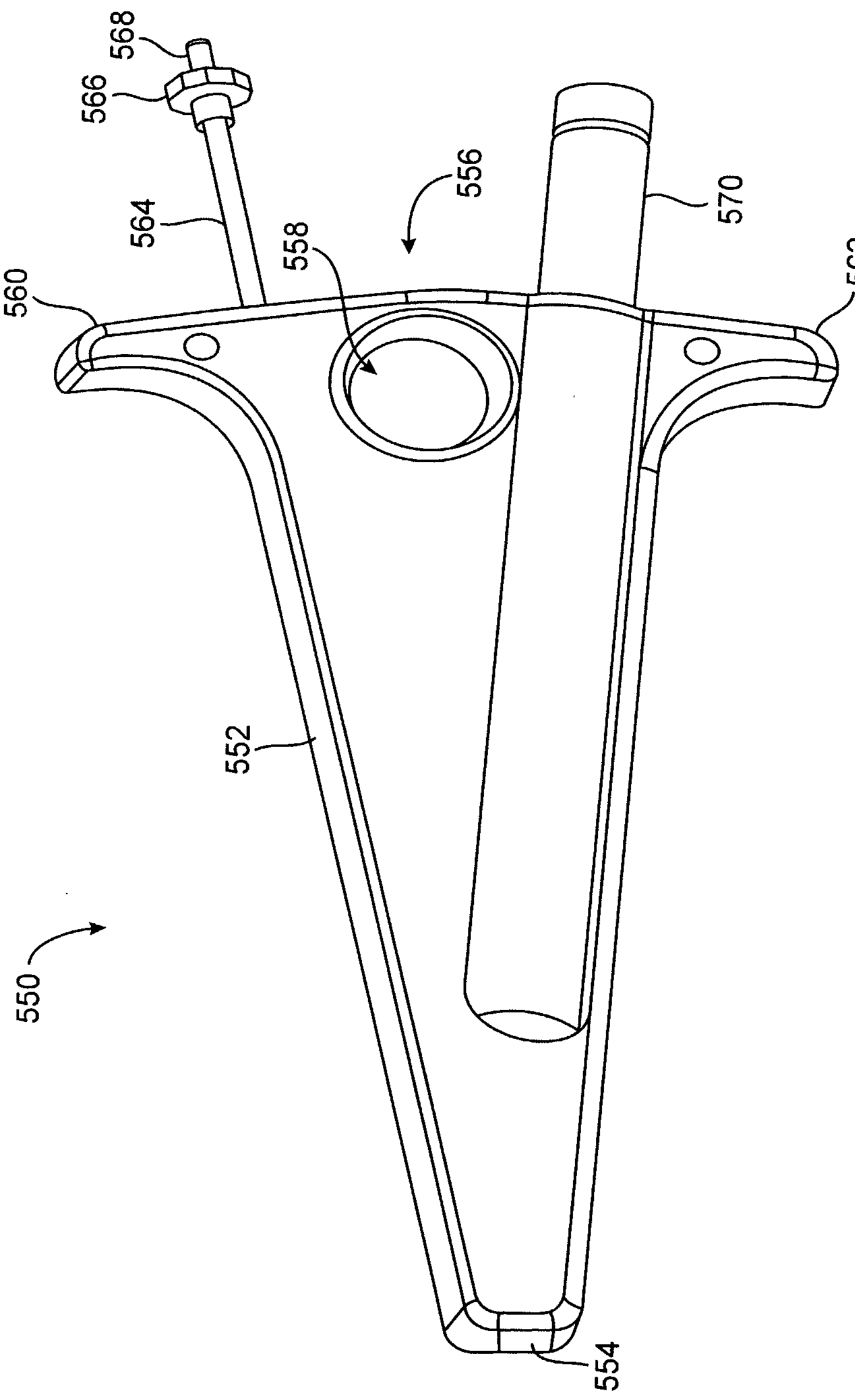

FIG. 19A

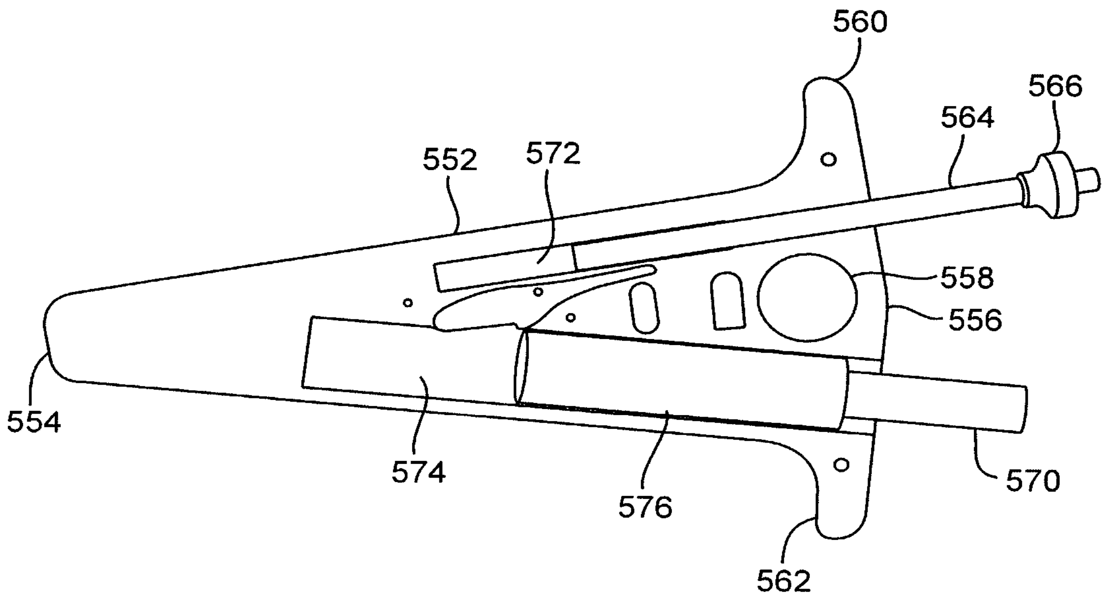

FIG. 19B

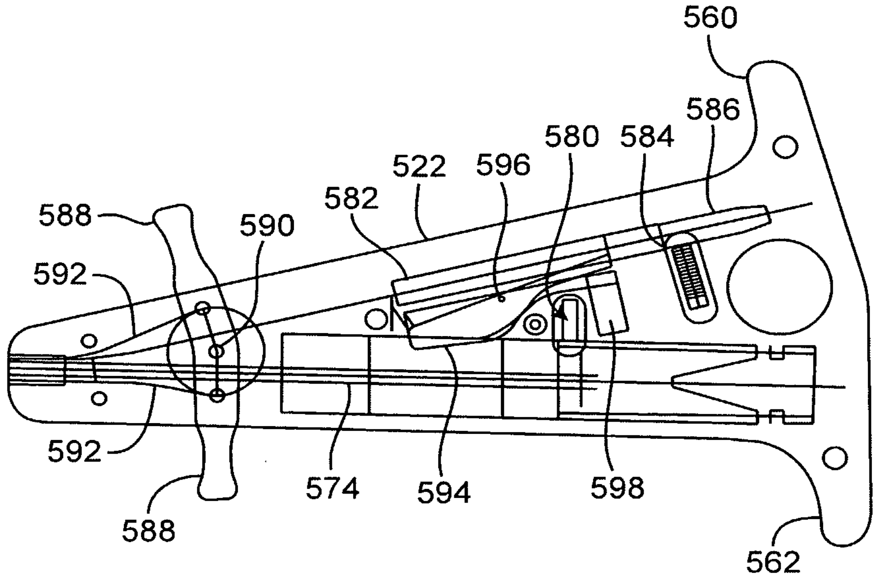

FIG. 20A

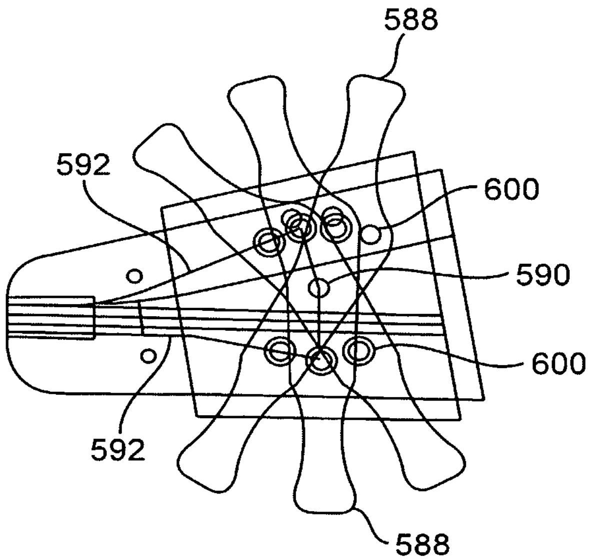

FIG. 20B

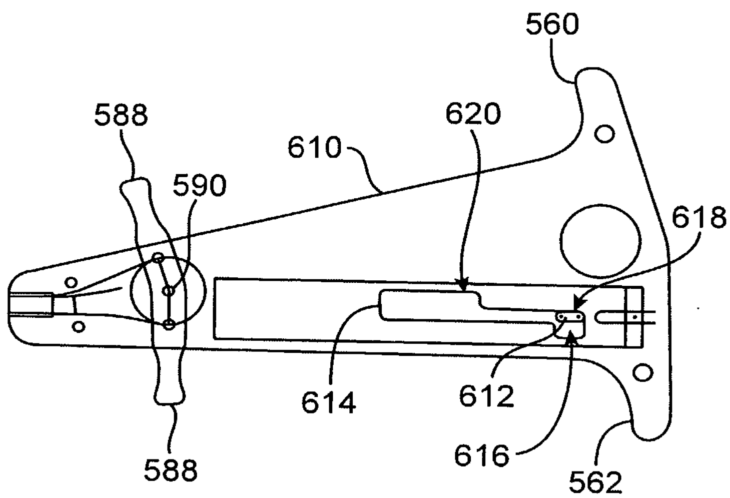

FIG. 21A

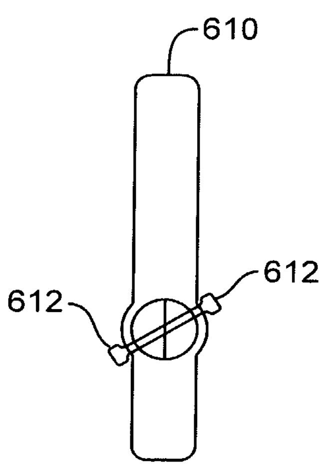

FIG. 21B

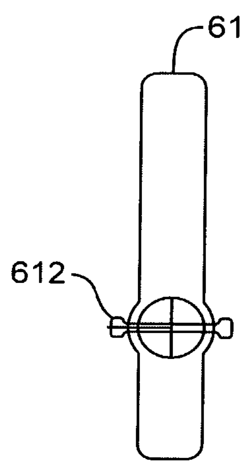

FIG. 21C

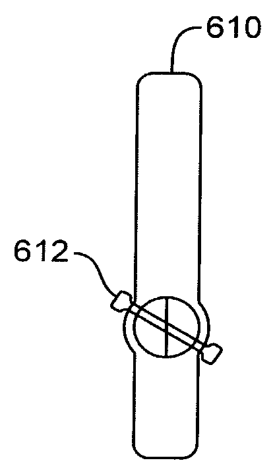

FIG. 21D

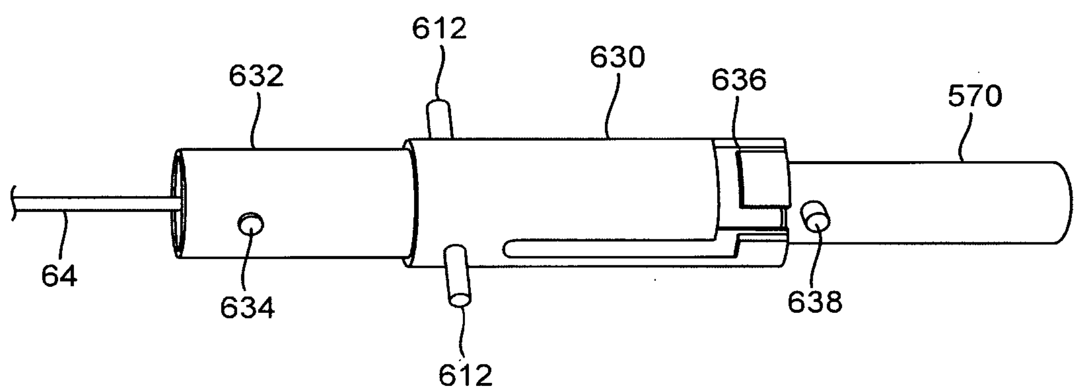

FIG. 22A

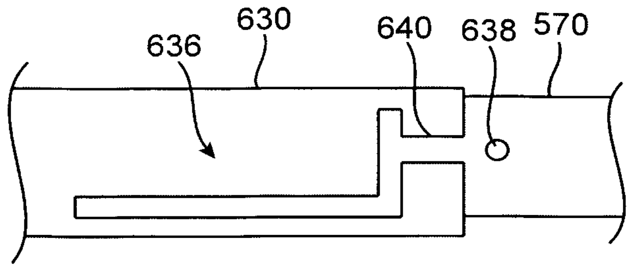

FIG. 22B

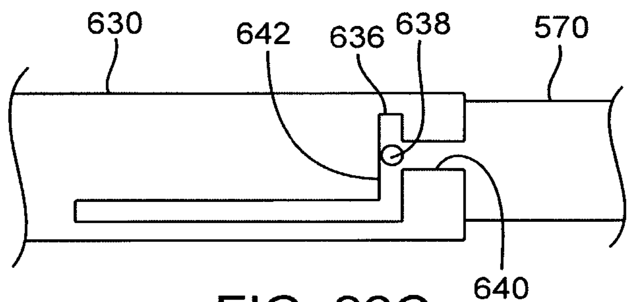

FIG. 22C

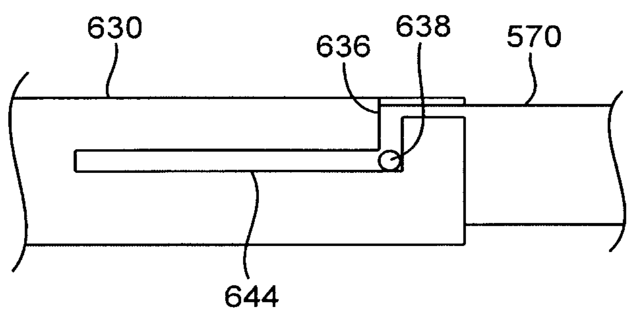

FIG. 22D

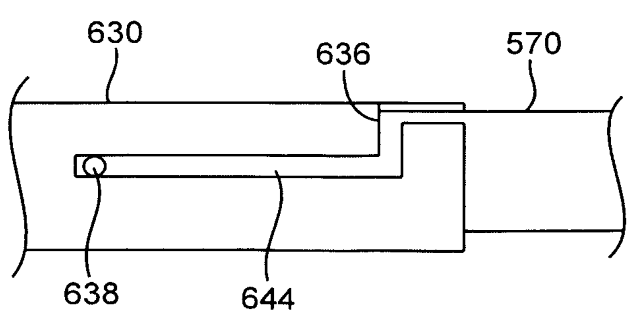

FIG. 22E

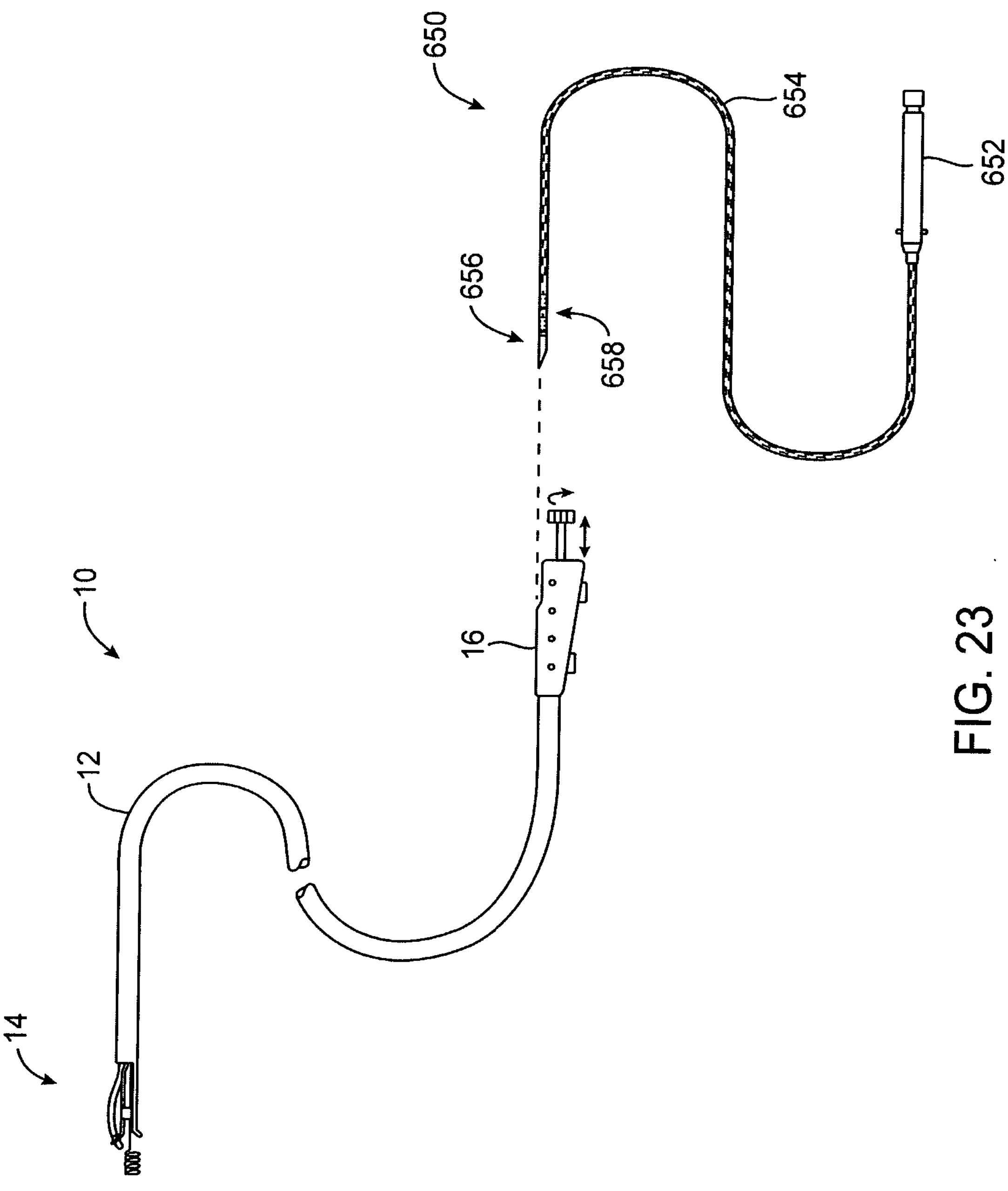

FIG. 23

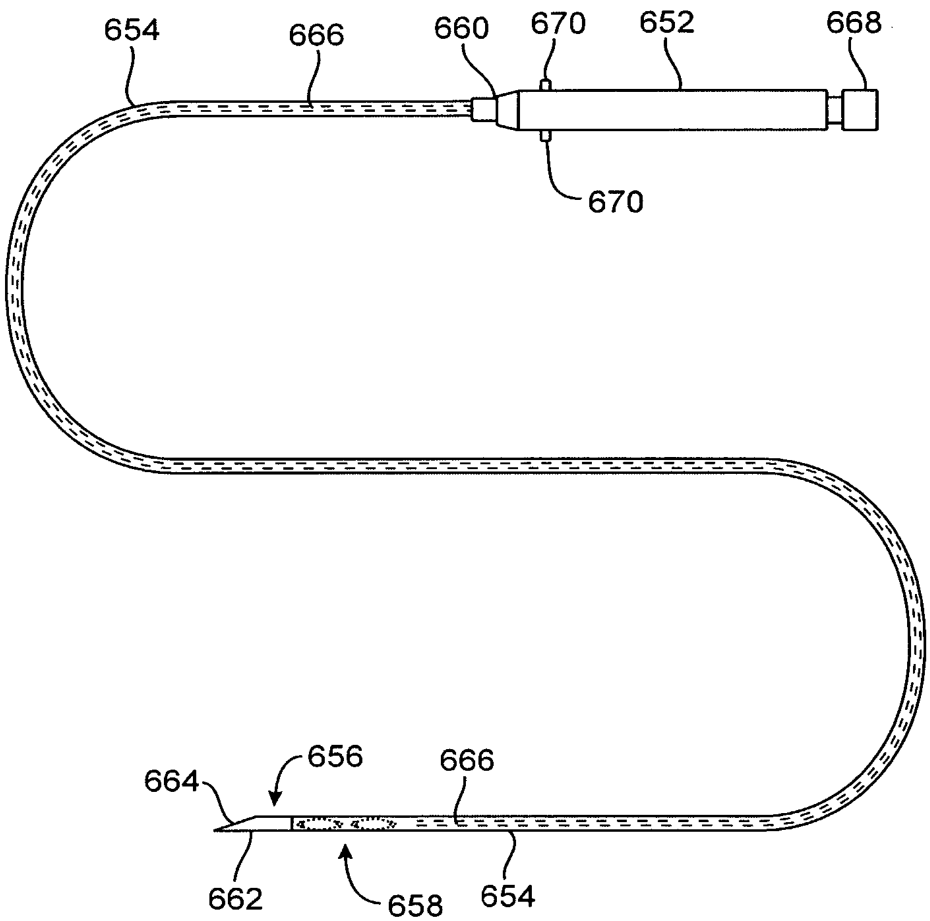

FIG. 24A

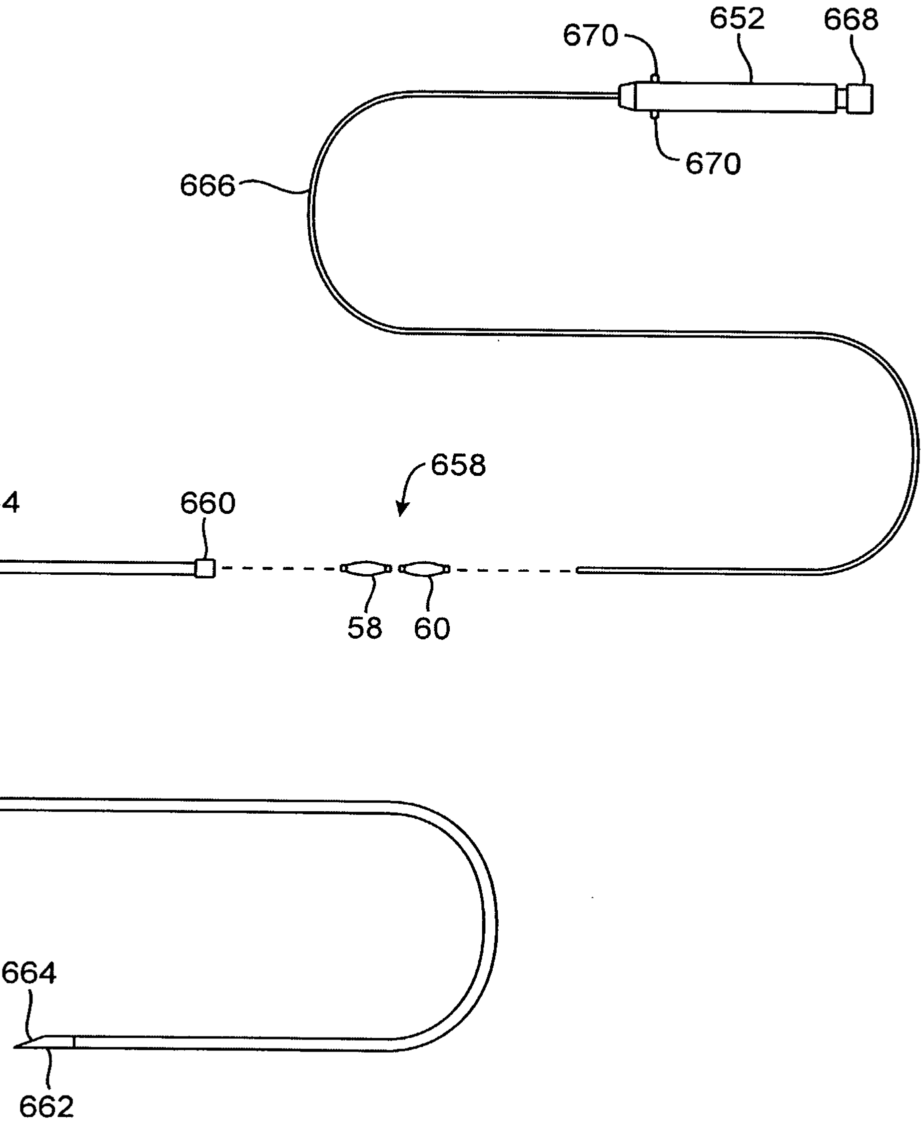

FIG. 24B

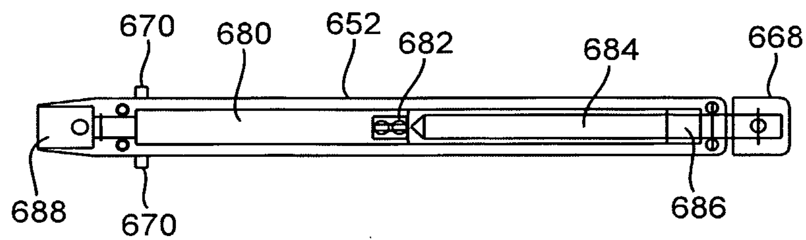

FIG. 25A

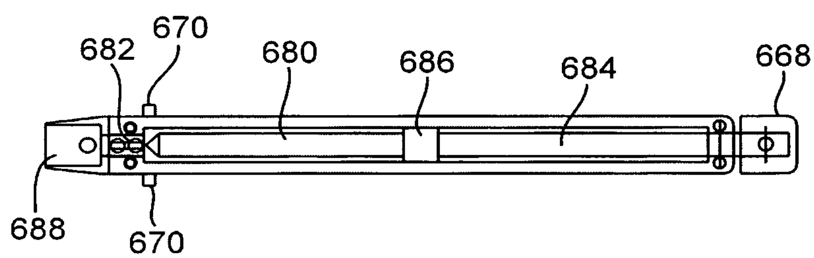

FIG. 25B

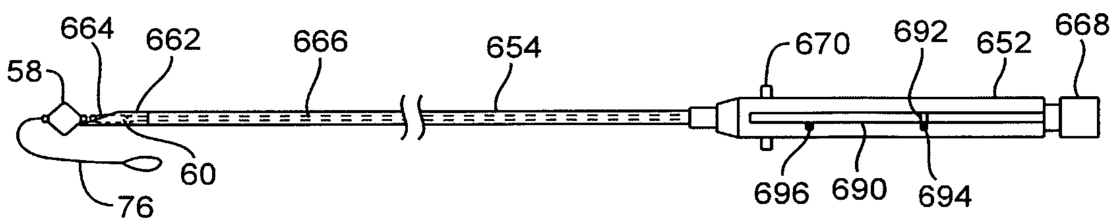

FIG. 26A

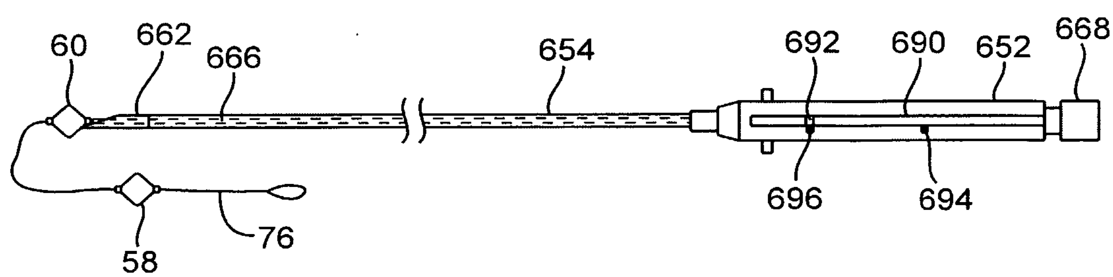

FIG. 26B

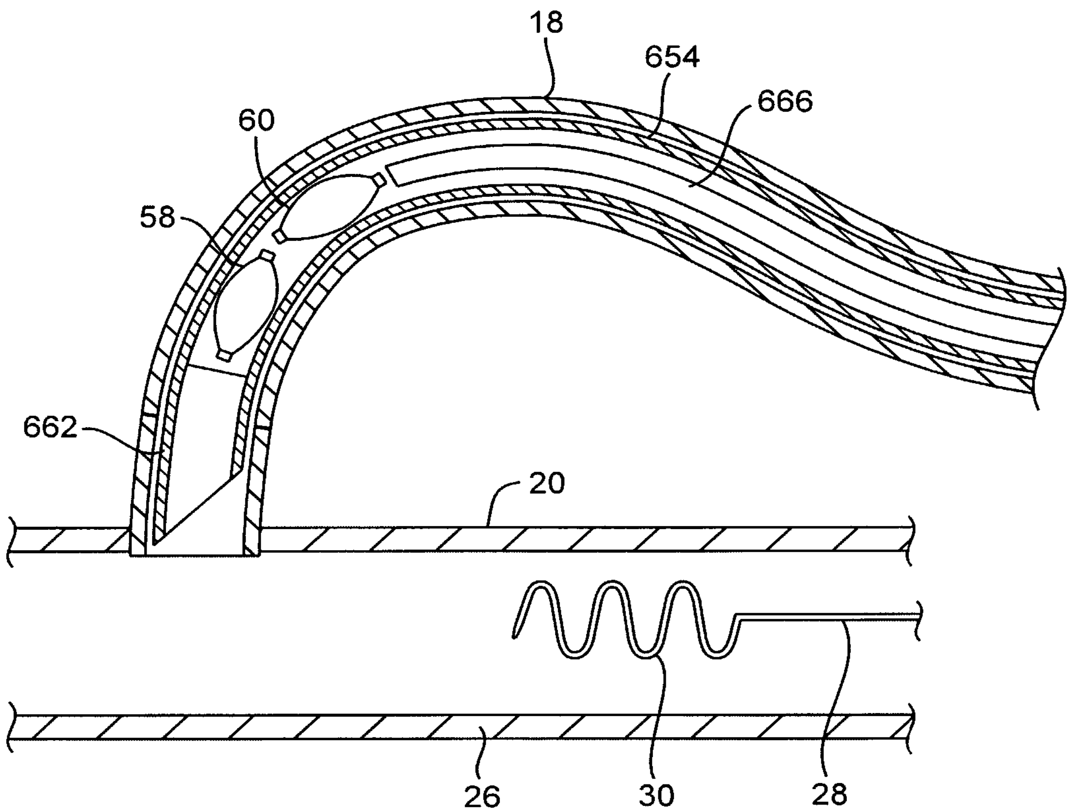

FIG. 26C

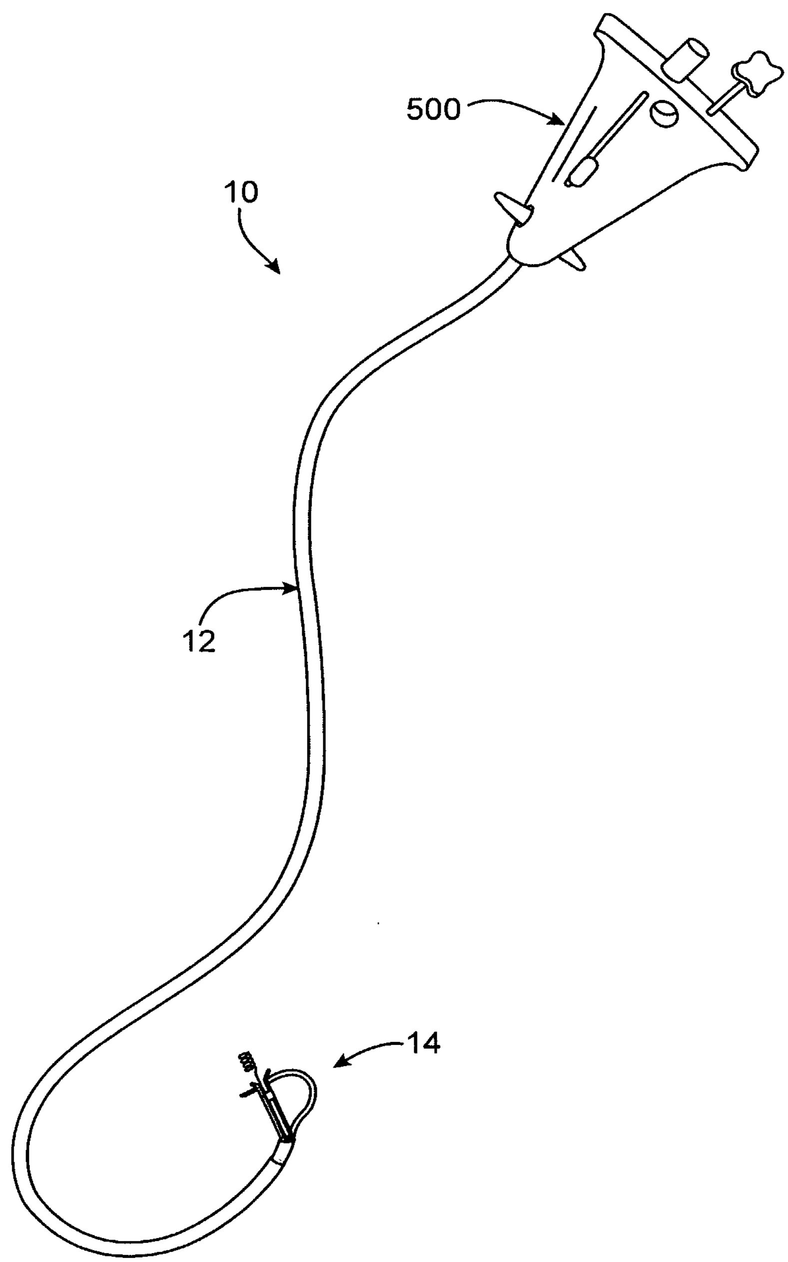

FIG. 27

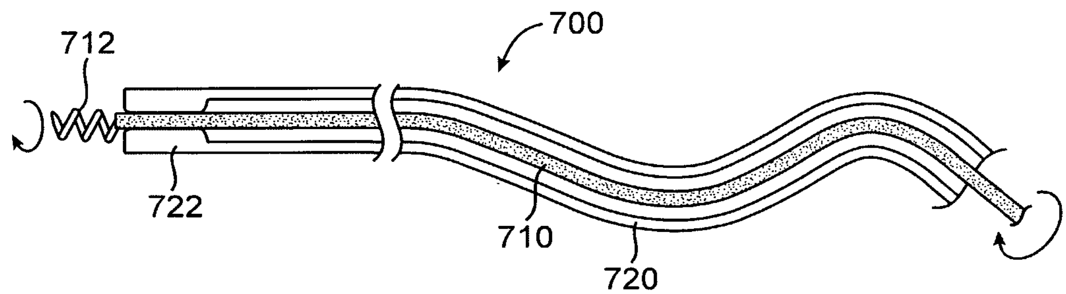

FIG. 28

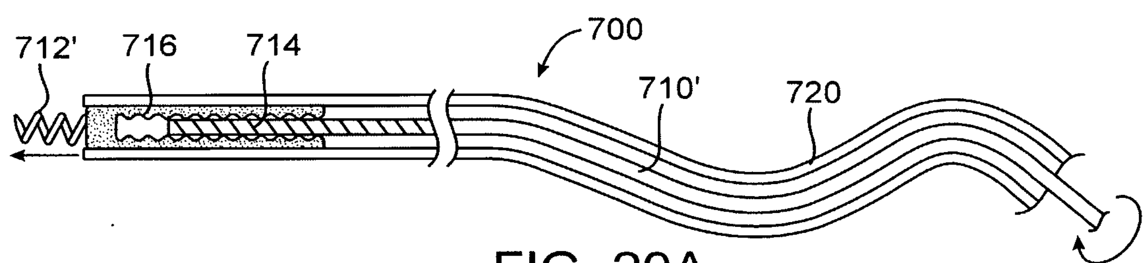

FIG. 29A

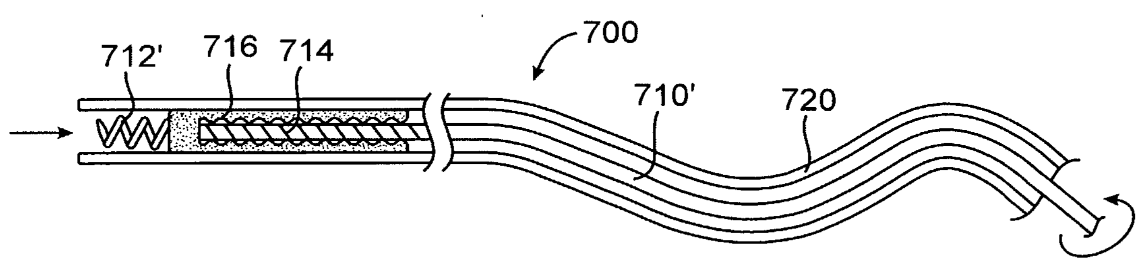

FIG. 29B

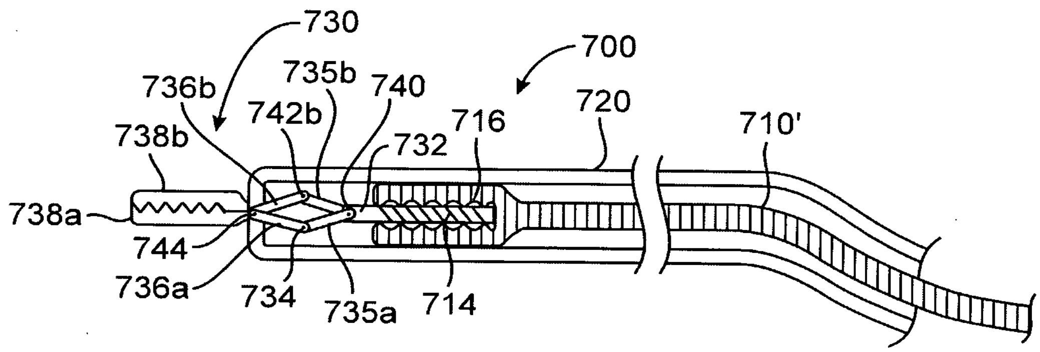

FIG. 30A

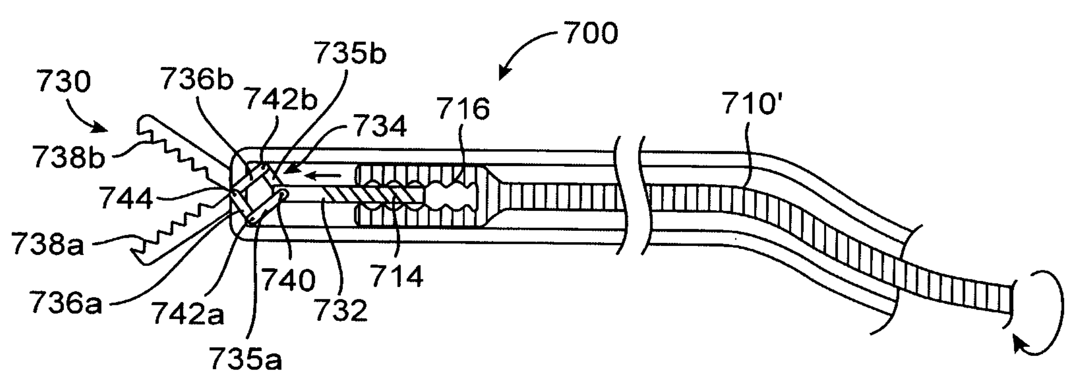

FIG. 30B

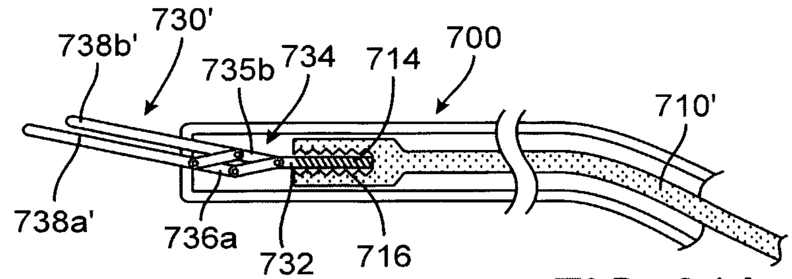

FIG. 31A

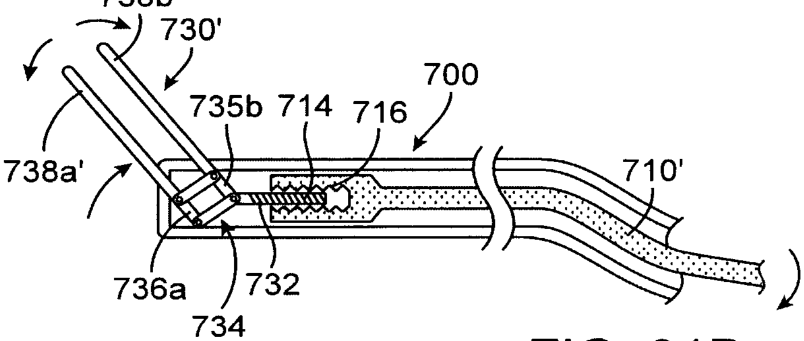

FIG. 31B

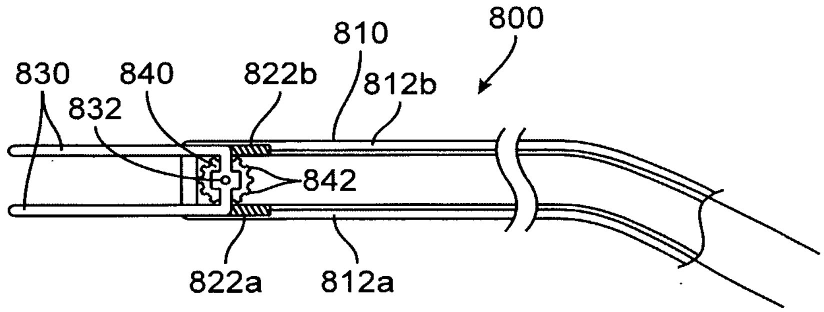

FIG. 32A

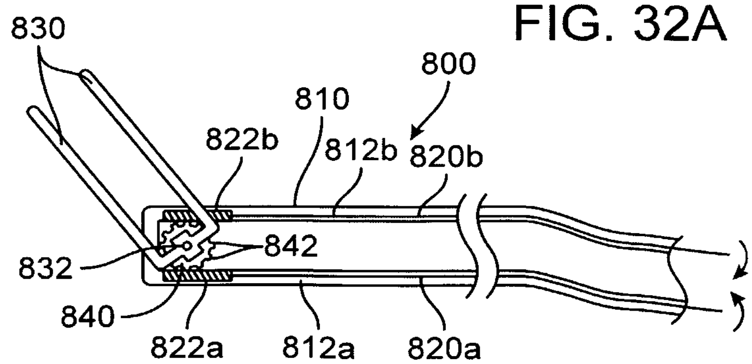

FIG. 32B

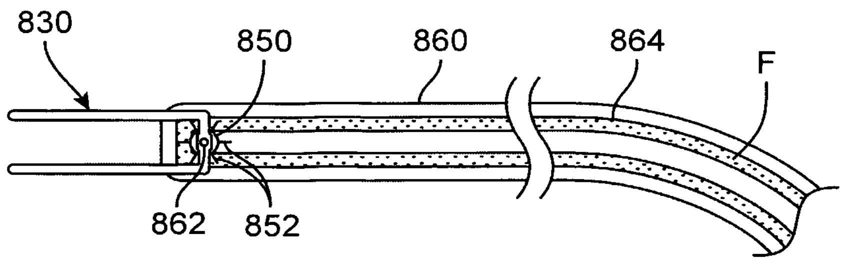

FIG. 33A

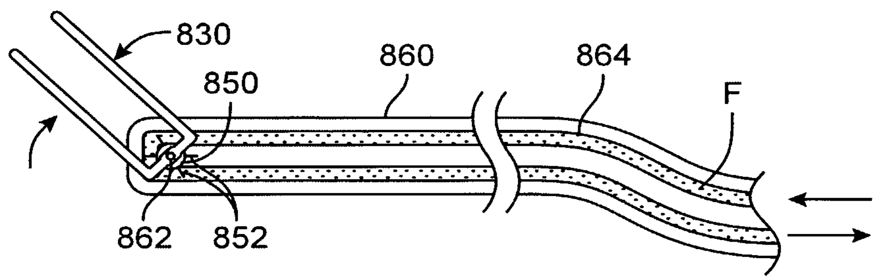

FIG. 33B

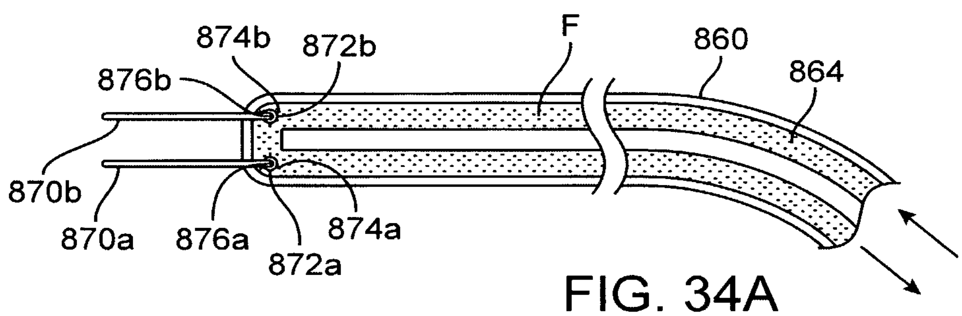

FIG. 34A

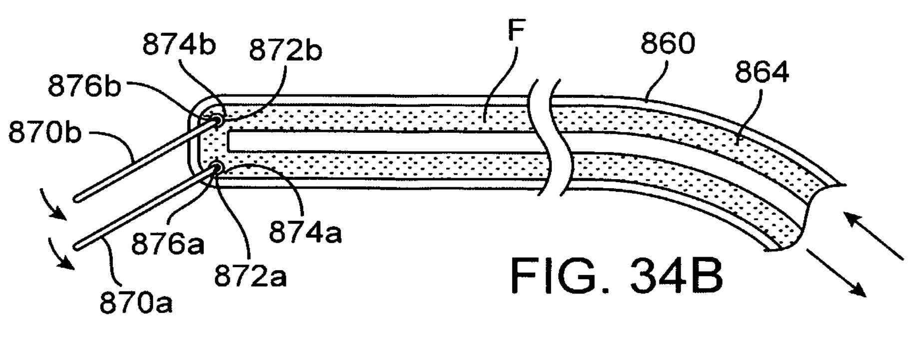

FIG. 34B

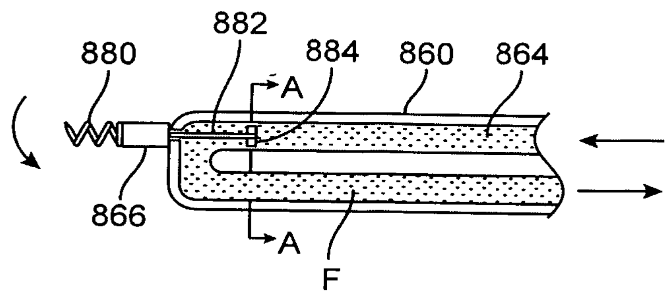

FIG. 35A

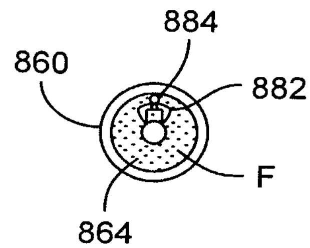

FIG. 35B

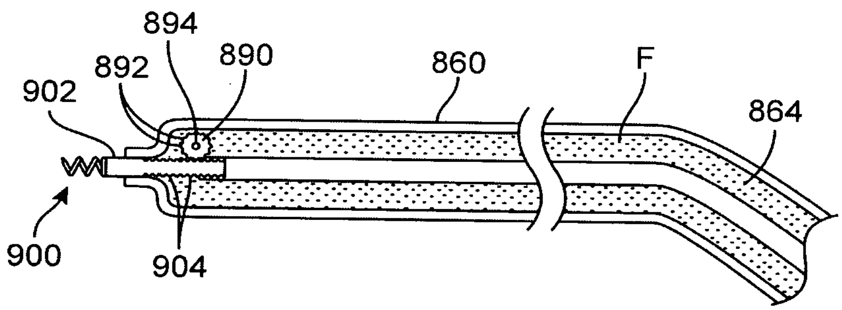

FIG. 36A

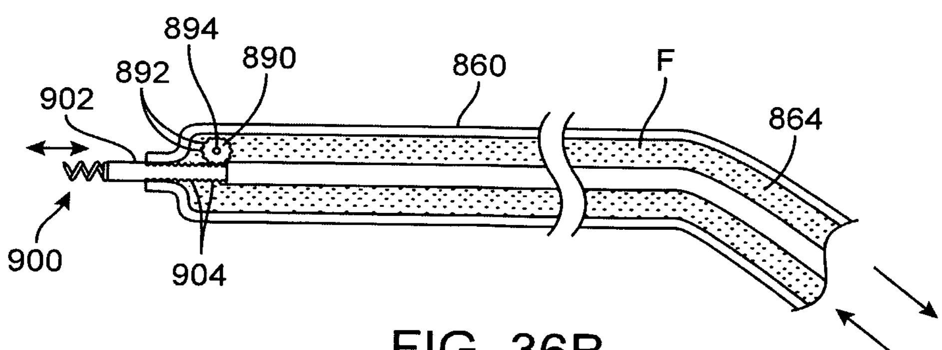

FIG. 36B

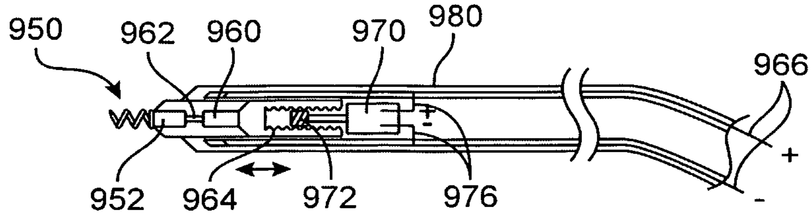

FIG. 37A

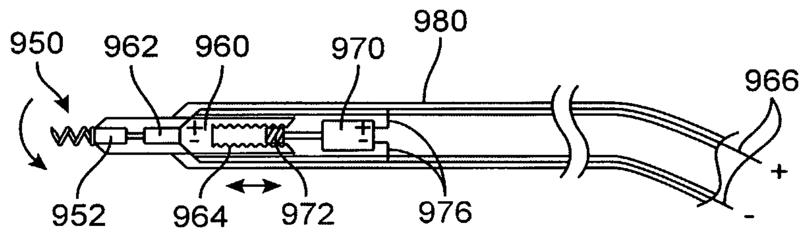

FIG. 37B

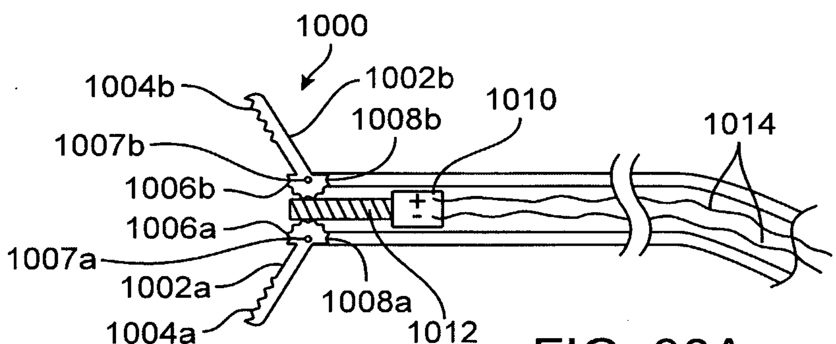

FIG. 38A

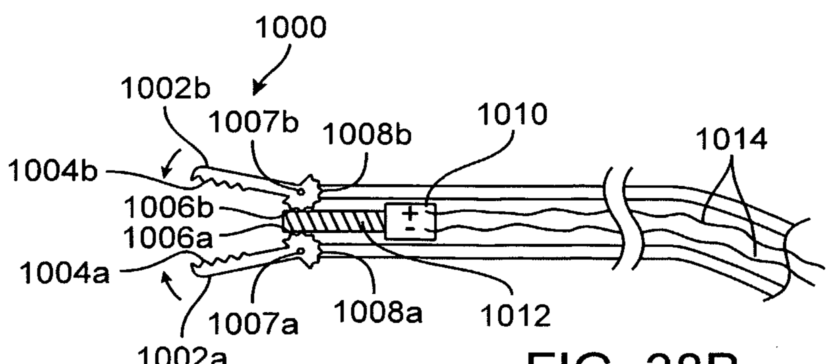

FIG. 38B

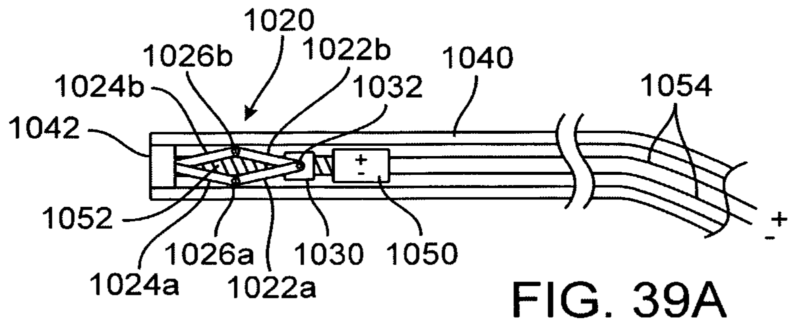

FIG. 39A

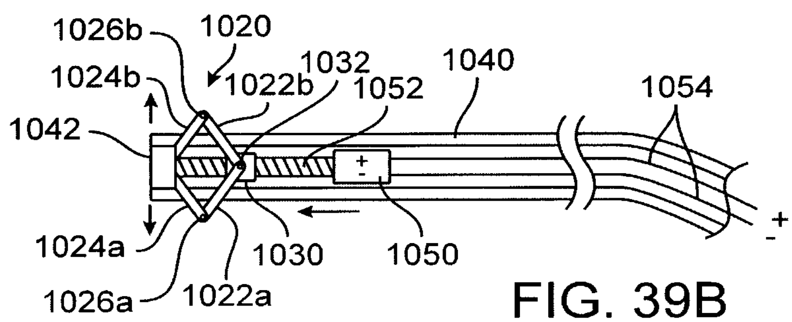

FIG. 39B

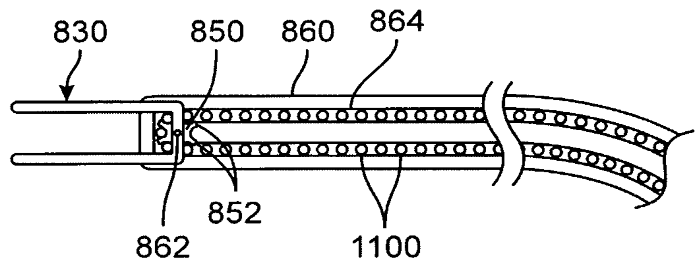

FIG. 40A

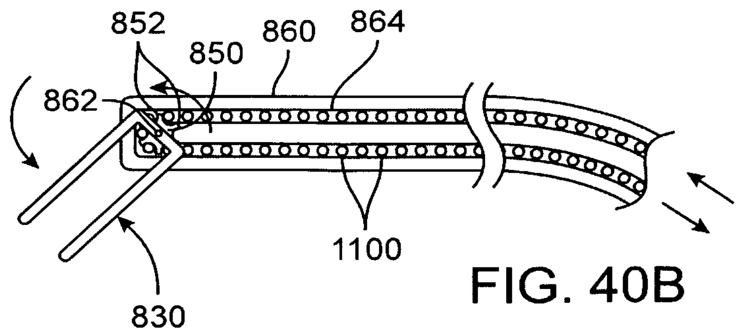

FIG. 40B

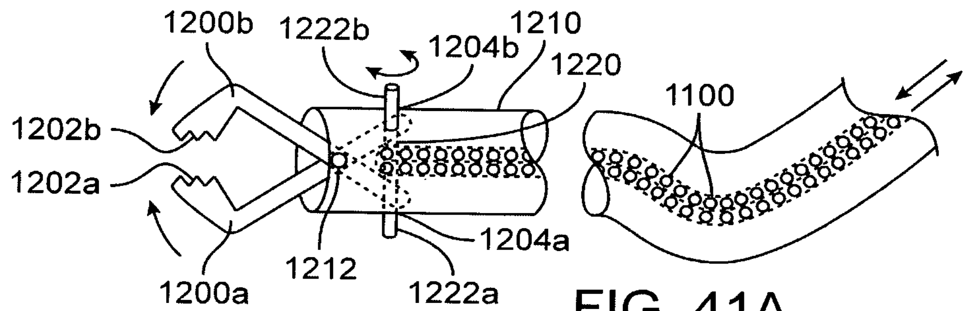

FIG. 41A

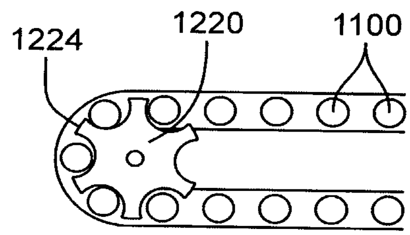

FIG. 41B

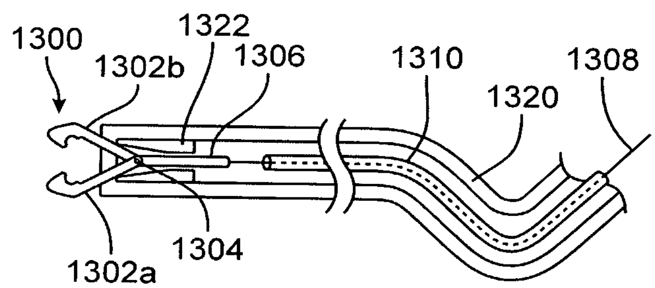

FIG. 42A

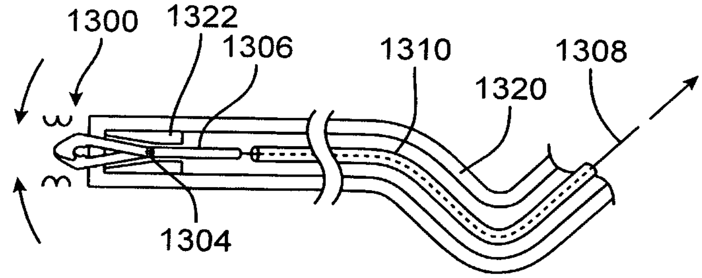

FIG. 42B

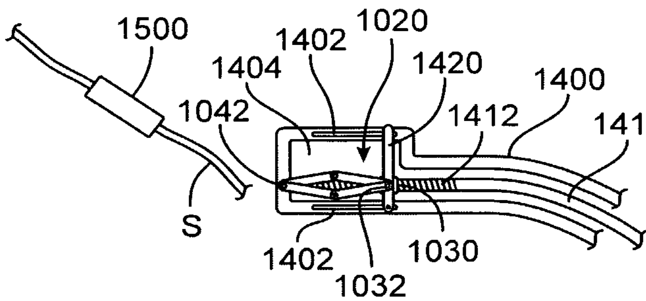

FIG. 43A

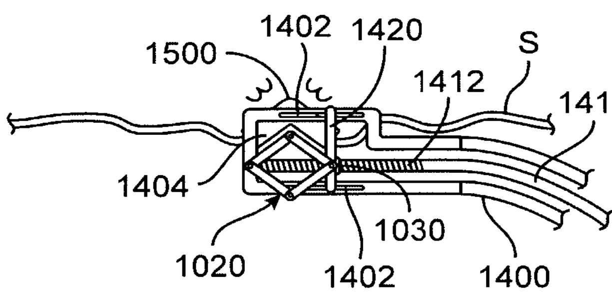

FIG. 43B

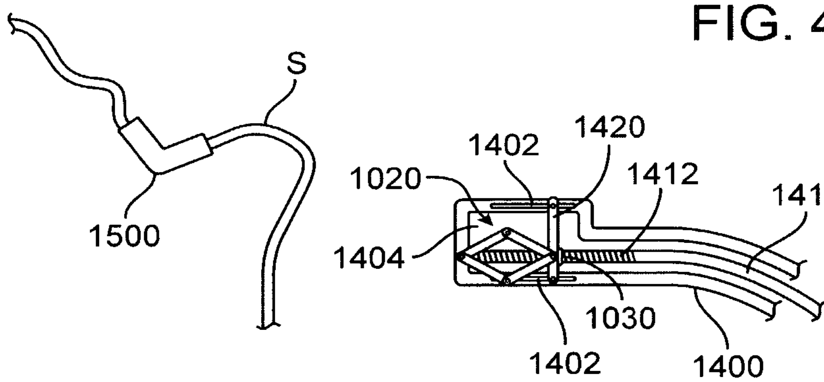

FIG. 43C

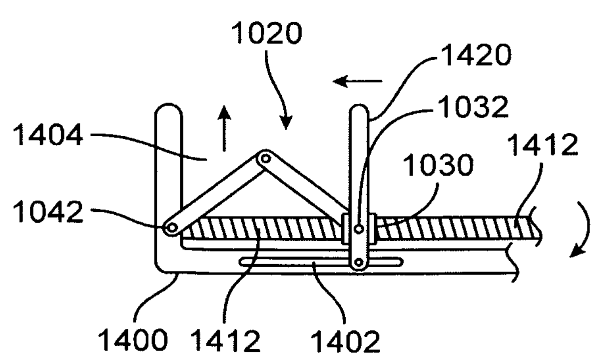

FIG. 43D

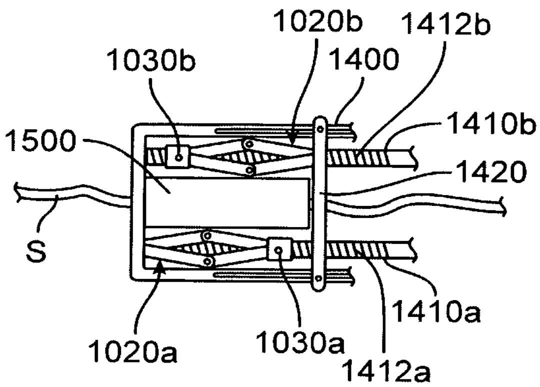

FIG. 44A

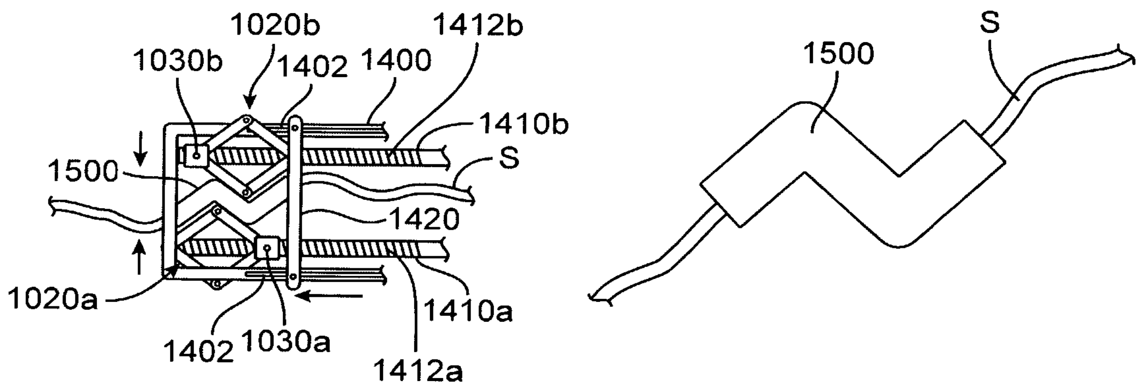

FIG. 44B

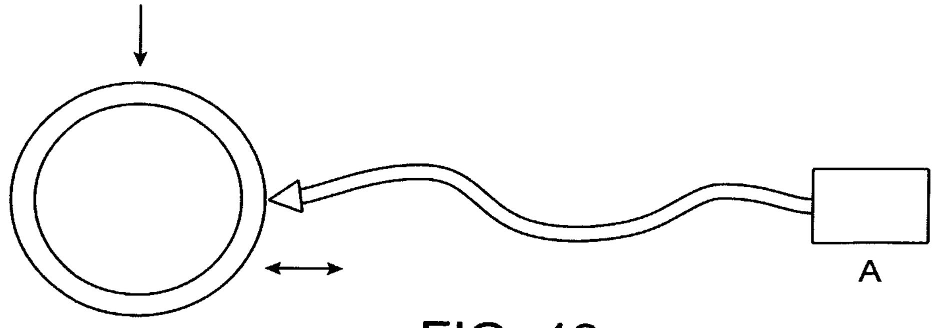

FIG. 46

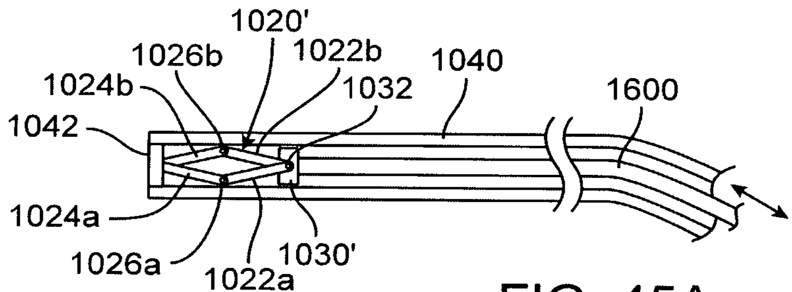

FIG. 45A

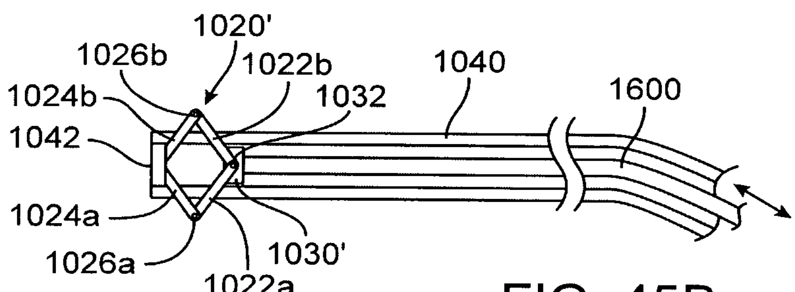

FIG. 45B